

## Results of Testing

### Results of Testing

| Chemical Name | CAS No. | Study Code/Type                                 | Protocol/Guideline  | Species                                 | Exposure                               | Dose/Concentration              | No. per Group         | Results  | Reference                                 |
|---------------|---------|---|---|---|--|---------------------------------|-----------------------|--|---|
| Acetonitrile  | 75-05-8 | HECTOXCARC<br>Carcinogenicity                   | National Toxicology<br>Program (NTP)                        | F344/N rats                             | inhalation, 6 hr/d, 5<br>d/wk, 2 years | 0, 100, 200, 400 ppm            | 56 male, 56<br>female | There was equivocal evidence of carcinogenic activity in male rats based on marginally increased incidences of hepatocellular adenoma and carcinoma. There was no evidence of carcinogenic activity in female rats exposed to 100, 200 or 400 ppm. There was an increased incidence of hepatic basophilic foci in male rats but not exposure-related liver lesions in female rats.   | NTP TR-447, April<br>1996                 |
| Acetonitrile  | 75-05-8 | HECTOXCARC<br>Carcinogenicity                   | NTP   | B6C3F <sub>1</sub> mice                 | inhalation, 6 hr/d, 5<br>d/wk, 2 years | 0, 50, 100, 200 ppm             | 60 male, 60<br>female | There was no evidence of carcinogenic activity in male and female mice exposed to 50, 100 or 200 ppm. There was an exposure-related increase of squamous hyperplasia of the forestomach in male and female mice.   | NTP TR-447, April<br>1996                 |
| Acetonitrile  | 75-05-8 | HEGTOXCHRM<br>Gene mutation                     | NTP   | Chinese<br>hamster ovary<br>(CHO)       | <i>in vitro</i>                        | Not specified                   | Not applicable        | A small increase in chromosomal aberrations occurred in the presence, but not in the absence, of S9.   | NTP TR-447, April<br>1996                 |
| Acetonitrile  | 75-05-8 | HEGTOXCHRM<br>Micronucleus test                 | NTP   | mice                                    | <i>in vitro</i>                        | Not specified                   | Not applicable        | A significant increase in micronucleated normochromatic erythrocytes was observed in mice treated with acetonitrile for 13 weeks. Female mice were not affected by exposure.   | NTP TR-447, April<br>1996                 |
| Acetonitrile  | 75-05-8 | HEGTOXCHRM<br>Gene mutation                     | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-42019) | Chinese<br>hamster ovary<br>(CHO)       | <i>in vitro</i>                        | 4-20 mg/mL                      | Not applicable        | Mutation frequencies at two of the sample concentrations in both the activated and the nonactivated Aroclor-induced S9 were higher than in the negative controls; however, analysis of variance on the combined data from replicated experiments indicated no significant differences.   | Fiche# OTS0507279<br>49 FR 44142; 11/2/84 |
| Acetonitrile  | 75-05-8 | HEGTOXMUTA<br>Mutagenicity study<br>(Ames test) | NTP   | <i>Salmonella</i><br><i>typhimurium</i> | <i>in vitro</i>                        | Not specified                   | Not applicable        | No mutagenic response observed either with or without S9 activation in <i>Salmonella typhimurium</i> strains TA97, TA98, TA100, TA1535, or TA1537.   | NTP TR-447, April<br>1996                 |
| Acetonitrile  | 75-05-8 | HERTOXTERA<br>Developmental<br>toxicity         | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-42019) | New Zealand<br>white rabbits            | days 6-18 of gestation                 | 0, 2.0, 15.0, 30.0<br>mg/kg/day | 25 (pregnant)         | Observations in dams of the high dose group included mortality (in 5 animals), thinning of the stomach wall in the cardiac region, ataxia, colored exudate, decreased motor activity, bradypnea, dyspnea, and impaired or loss of righting reflex. An increase in the incidence of an extra ossification site in the parietal bones was observed in four fetuses in two high dose groups, however this frequency was considered to be a spontaneous effect in this strain of rabbit. | Fiche# OTS0507279<br>49 FR 44142; 11/2/84 |

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|---------------|---------|--|--|--------------------------|---------------------------------------|--|-----------------------|--|---|
| Acrylamide    | 79-06-1 | HECTOXCARC<br>Chronic/oncogenicity<br>toxicity<br>(Voluntary test) | Non-TSCA Protocol/<br>Guideline (see<br>docket# 80T-127)         | rats                     | 2 year, oral (drinking<br>water)      | 0, 0.01, 0.1, 0.5,<br>2.0 mg/kg/dy       | 60 male;<br>60 female | Observations of test animals receiving 2.0 mg/kg/day included an increase in mortality (about the 21st month) and degeneration of the peripheral nerves. The females of this group had increased tibial nerve degeneration. In addition, this same dose level produced an increase in tumor incidence in both males and females. In the female, the sites of increased tumors included: mammary gland (benign and malignant), clitoral gland (benign), uterus (malignant), and the oral cavity (benign). In the males and females, the site of increased tumors were at the thyroid gland (malignant and benign). Males receiving 0.5 mg/kg/day had a significant increase in the incidence of scrotal mesothelioma (malignant). | Fiche# OTS0507273<br>50 FR 5421; 2/6/85       |
| Acrylamide    | 79-06-1 | EEATOX<br>Aquatic toxicity<br>(Voluntary test)                     | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>47003B) | Bluegill sunfish         | 96 hr, flow-through                   | 14, 35, 81, 150, 350<br>mg/L             | Not specified         | The no-observed-effect concentration (NOEL) was 35 mg/L. The LC <sub>50</sub> value with its corresponding 95% confidence interval was 100 mg/L and 81 to 150 mg/L, respectively. Behavioral observations included surfacing and loss of equilibrium of the test animals, followed by death.   | Fiche# OTS0507314<br>48 FR 34119; 7/27/83     |
| Acrylamide    | 79-06-1 | EEATOX<br>Aquatic toxicity<br>(Voluntary test)                     | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>47003B) | Fathead<br>minnow        | 96 hr, flow-through                   | 21, 41, 77, 160, 340<br>mg/L             | Not specified         | The no-observed-effect concentration was 41 mg/L. Observations included loss of equilibrium and surfacing of the test animals, followed by death. The LC <sub>50</sub> value with its corresponding 95% confidence interval was 120 mg/L and 77 to 160 mg/L, respectively.   | Fiche# OTS0507315<br>48 FR 34119; 7/27/83     |
| Acrylamide    | 79-06-1 | EEATOX<br>Aquatic toxicity<br>(Voluntary test)                     | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>47003B) | Rainbow trout            | 96 hr, flow-through                   | 17, 37, 74, 150, 370<br>mg/L             | Not specified         | The no-observed-effect concentration was 37 mg/L. Observations included loss of equilibrium and surfacing of the test animals, followed by death. The LC <sub>50</sub> value with its corresponding 95% confidence interval was 110 mg/L and 74 to 150 mg/L, respectively.   | Fiche# OTS0507317<br>48 FR 34119; 7/27/83     |
| Acrylamide    | 79-06-1 | EEATOX<br>Aquatic toxicity<br>(Voluntary test)                     | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>47003B) | <i>Daphnia<br/>magna</i> | 48 hr, flow-through                   | 15, 25, 60, 110, 270<br>mg/L             | Not specified         | Observation included migration of test animals to the bottom of test chambers with little movement until death. The no-observed-effect concentration was 60 mg/L. The LC <sub>50</sub> and its corresponding 95% confidence interval were determined to be 160 mg/L and 110 to 270 mg/L, respectively.   | Fiche# OTS0507316<br>48 FR 34119; 7/27/83     |
| Acrylamide    | 79-06-1 | EEATOX<br>Aquatic toxicity<br>(Voluntary test)                     | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>47003B) | Mysid shrimp             | 96 hr, flow-through,<br>seawater      | 5.21, 13.58, 35.50,<br>78.68, 160.90 ppm | Not specified         | Mortality of Mysid shrimp increased as the duration of exposure increased. After 96 hours, mortality ranged from 0% in the 5.21 ppm test concentration to 100% in the 160.90 ppm test concentrations. No mortality occurred in the control during the test. The calculated LC <sub>50</sub> value was 78 ppm with a 95% confidence limit of 65 to 92 ppm. The no-observed-effect concentration after the 96 hour exposure was 5.21 ppm (tests were performed in seawater).   | Fiche# OTS0510507<br>51 FR 16203; 5/1/86      |
| Acrylamide    | 79-06-1 | EECTOX<br>Chronic/aquatic<br>toxicity<br>(Voluntary test)          | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>47003B) | Mysid shrimp             | 28 days (life-cycle),<br>flow-through | 0.06 to<br>4.40 mg/L                     | Not specified         | Mortality at the highest concentration (4.40 mg/L) reached 45%, which was statistically greater than the controls. The test animals reproductive cycles were not adversely affected by any of the test concentrations. There were no significant delays in time of release of the first brood at any of the test concentrations.   | Fiche# OTS0510508<br>51 FR 39799;<br>10/31/86 |

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| Chemical Name   | CAS No.  | Study Code/Type   | Protocol/Guideline   | Species                                      | Exposure  | Dose/Concentration   | No. per Group  | Results   | Reference                                  |
|---|----------|---|--|--|---|--|----------------|---|--|
| 2-Ethylhexanol<br>[related to Di(2-ethylhexyl) phthalate] | 104-76-7 | HECTOXRFM<br>Morphological transformation<br>(Voluntary test) | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | mice, BALB 3T3 cells                         | <i>in vitro</i>   | 0.188, 0.375, 0.75, 1.125, 1.5 µl/ml   | Not applicable | The test material, 2-EH, did not induce an increased number of transformed foci at any of the concentrations tested, with or with activation.   | 48 FR 12124; 3/23/83<br>Fiche# OTS0508477  |
| 2-Ethylhexanol<br>[related to Di(2-ethylhexyl) phthalate] | 104-76-7 | HEGTOXCHRM<br>Chromosomal study<br>(Voluntary test)           | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | mice   | intraperitoneal (i.p.), single dose, 2-doses; 24 hr apart | 456 mg/kg/d  | Not specified  | The test material, 2-EH, did not induce significant differences in the percent micronucleated polychromatic erythrocytes in test animals. The test material was not considered to be clastogenic in this study. | 48 FR 12124; 3/23/83<br>Fiche# OTS0508477  |
| 2-Ethylhexanol<br>[related to Di(2-ethylhexyl) phthalate] | 104-76-7 | HEGTOXMUTA<br>Mutagenicity study<br>(Voluntary test)          | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Salmonella typhimurium</i> strains        | <i>in vitro</i>   | 0.002-1.80 µl/plate  | Not applicable | The test material, 2-EH, did not induce genetic activity in any of the tester strains (TA 98, TA 100, TA 1535, TA 1537, TA 1538) in either the absence or presence of metabolic activation                      | 48 FR 12124; 3/23/83<br>Fiche# OTS0508477  |
| 2-Ethylhexanol<br>[related to Di(2-ethylhexyl) phthalate] | 104-76-7 | HEGTOXMUTA<br>Mutagenicity study                              | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Chinese hamster ovaries (CHO)                | <i>in vitro</i>   | 20-300 nl/ml (nonactivation); 100-400 nl/ml (activation)                       | Not applicable | The test material, 2-EH, did not induce dose-related increases in mutant frequency, with or without activation. Dose-related effects included decreased survival and relative population growth.                | 51 FR 6468; 2/24/86<br>Fiche# OTS0509537   |
| 2-Ethylhexanol<br>[related to di(2-ethylhexyl) phthalate] | 104-76-7 | HEGTOXMUTA<br>Mutagenicity study<br>(Voluntary test)          | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Chinese hamster ovaries (CHO)                | <i>in vitro</i>   | 20-300 nl/ml (nonactivation); 100-400 nl/ml (activation)                       | Not applicable | The test material, 2-EH, did not induce dose-related increases in mutant frequency, with or without activation. Dose-related toxicity was observed.   | 50 FR 1892; 5/3/85<br>Fiche# OTS0508498    |
| Dibutyl phosphate   | 107-66-4 | EEATOX<br>Algae acute toxicity<br>(Voluntary test)            | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Green alga                                   | static, 6 days  | 0.05-1409.4 ppm  | Not applicable | Toxic to the test algae. The EC <sub>50</sub> (population growth) value is 0.2 mg/L.  | 50 FR 5421; 2/6/85<br>Fiche# OTS0508496    |
| Di(2-ethylhexyl) phthalate                                | 117-81-7 | EEATOX<br>Acute fish toxicity                                 | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Sheepshead minnow                            | flow-through, 96 hr                                       | 0.08-60 ppm (measured)   | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 49 FR 44142; 11/2/84<br>Fiche# OTS0508492  |
| Di(2-ethylhexyl) phthalate                                | 117-81-7 | EEATOX<br>Acute fish toxicity                                 | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Rainbow trout                                | flow-through, 96 hr                                       | 0.013-100 mg/L (measured)  | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 49 FR 18779; 5/2/84<br>Fiche# OTS0508486   |
| Di(2-ethylhexyl) phthalate                                | 117-81-7 | EEATOX<br>Acute chironomid toxicity                           | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Paratanytarsus parthenogenica</i> (midge) | static, 48 hr   | 0.056-86.3 mg/L (measured)   | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 49 FR 30114; 7/26/84<br>Fiche# OTS0508488  |
| Di(2-ethylhexyl) phthalate                                | 117-81-7 | EEATOX<br>Acute fish toxicity                                 | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Fathead minnow                               | flow-through, 96 hr                                       | 0.026-34 mg/L (measured)   | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 48 FR 53159; 11/25/83<br>Fiche# OTS0508481 |
| Di(2-ethylhexyl) phthalate                                | 117-81-7 | EEATOX<br>Acute mysid shrimp toxicity                         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Mysid shrimp                                 | static, 96 hr   | 0.056-86.0 mg/L (measured)   | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 49 FR 30114; 7/26/84<br>Fiche# OTS0508488  |
| Di(2-ethylhexyl) phthalate                                | 117-81-7 | EEATOX<br>Acute fish toxicity                                 | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Bluegill                                     | static, 96 hr   | 0.34-1.0 mg/L (measured)   | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 48 FR 53159; 11/25/83<br>Fiche# OTS0508481 |
| Di(2-ethylhexyl) phthalate                                | 117-81-7 | EEATOX<br>Acute fish toxicity                                 | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Fathead minnow                               | static, 96 hr   | <0.0037 to 210 mg/L (5 concentrations/test material up to limit of solubility) | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 48 FR 53159; 11/25/83<br>Fiche# OTS0508481 |

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|----------------------------|----------|--|--|----------------------|--|--|--------------------------------|--|---|
| Di(2-ethylhexyl) phthalate | 117-81-7 | EEATOX<br>Algae acute toxicity                   | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Green alga           | static, 6 days   | 0.05-1409.4 ppm                                      | Not applicable                 | No acute toxicity below the limit of aqueous solubility.   | 50 FR 5421; 2/6/85<br>Fiche# OTS0508496   |
| Di(2-ethylhexyl) phthalate | 117-81-7 | EEATOX<br>Daphnid acute toxicity                 | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Daphnia magna</i> | static, 48 hr  | 5 concentrations up to water solubility limits       | Not specified                  | The 48-hour LC <sub>50</sub> value is >0.32 mg/L.  | 49 FR 44142; 11/2/84<br>Fiche# OTS0508492 |
| Di(2-ethylhexyl) phthalate | 117-81-7 | EECTOX<br>Chronic daphnid toxicity               | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Daphnia magna</i> | flow-through, 21 days  | 0.015-80 mg/L (measured)                             | Not specified                  | Non-toxic.   | 50 FR 5421; 2/6/85<br>Fiche# OTS0508496   |
| Di(2-ethylhexyl) phthalate | 117-81-7 | EFBDEG<br>Biodegradation study                   | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable       | shake flask, 28 days, CO by GC   | 4 mg carbon/equivalent                               | Not applicable                 | Primary biodegradation of 90% or higher and ultimate biodegradation of 55%.  | 48 FR 53159; 11/25/83<br>OTS508481        |
| Di(2-ethylhexyl) phthalate | 117-81-7 | EFBDEG<br>Biodegradation study                   | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable       | 23° C, 24 hr, CO <sub>2</sub> by GC  | 1 mg/L   | Not applicable                 | Exhibited at least 50% primary degradation in 24 hours.  | 49 FR 44142; 11/2/84<br>Fiche# OTS0508490 |
| Di(2-ethylhexyl) phthalate | 117-81-7 | EFCHWSOL<br>Water solubility                     | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable       | deionized water, well and sea water; equilibrate for 24 h at 25 ± 2° C; analysis by GC | Not specified  | Not applicable                 | Solubilities for distilled, well and sea water of 0.34 ± 0.04, 0.30 ± 0.05, and 0.16 ± 0.04 mg/L, respectively.  | 48 FR 34119; 7/27/83<br>Fiche# OTS0508479 |
| Di(2-ethylhexyl) phthalate | 117-81-7 | EFPCHEVPRE<br>Vapor Pressure                     | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable       | 25 °C, analysis by GC  | Not specified  | Not applicable                 | Vapor pressure = 8.6 x 10 <sup>-4</sup> .  | 49 FR 44124; 11/2/84<br>Fiche# OTS0508490 |
| Di(2-ethylhexyl) phthalate | 117-81-7 | EFTSPT<br>Sediment adsorption isother            | 796.2750 (modified)  | Not applicable       | Not specified  | 0.006, 0.025, 0.041, 0.075, 0.099, 0.141 ml aliquots | Not applicable                 | The mean percents adsorbed to sediments EPA 8, EPA 18, EPA 21 were 70.2%, 90.6%, and 92.0%, respectively. Correlation coefficients were 0.9606, 0.9539, and 0.9857 for sediments EPA 8, EPA 18, and EPA 21, respectively. HPLC analysis of aqueous adsorption phases and sediment extracts demonstrated stability. The mean C14-mass balance accountabilities were 102%, 107%, and 107% for sediments EPA 8, EPA 18, EPA 21, respectively. | 56 FR 42623; 8/28/91<br>Fiche# OTS0533017 |
| Di(2-ethylhexyl) phthalate | 117-81-7 | HEADME<br>Metabolism study                       | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | monkeys, rats, mice  | oral (gavage), single dose   | 100 mg/kg  | 3 monkeys, 5 male rats, 5 mice | 30 to 40% of the dose of DEHP was excreted in the urine during the first 12 hours for rats and mice, and during the first 24 hours for monkeys. Approximately 50% of the dose was excreted in the feces, primarily in the first 24 hours for rats and mice, and 48 hours for monkeys. Recoveries of the labelled test material administered were 79, 87, and 90% for monkeys, rats, and mice, respectively.                                | 50 FR 5421; 2/6/85<br>Fiche# OTS0508494   |
| Di(2-ethylhexyl) phthalate | 117-81-7 | HEGTOXCHRM<br>Chromosomal study (Voluntary test) | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | mice                 | intraperitoneal (i.p.), single dose, 2-doses; 24 hr apart                              | 5 g/kg/day   | Not specified                  | The test material, DEHP, did not induce micronuclei in the bone marrow of the test animals. There was no significant difference in the percent micronucleated polychromatic erythrocytes between the test animals and the controls. The test material was therefore non-clastogenic in this study.   | 48 FR 12124; 3/23/83<br>Fiche# OTS0508477 |

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|----------------------------|----------|---|--|--------------------------------|-------------------------|---|---------------------|--|---|
| Di(2-ethylhexyl) phthalate | 117-81-7 | HEGTOXDNAF<br>Unscheduled DNA synthesis<br>(Voluntary test) | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | rat primary hepatocytes        | <i>in vitro</i>         | 5, 10, 25, 50 100, 250, 500, 1000 nl/ml                       | Not specified       | The test material, DEHP, did not induce significant changes in the nuclear labelling of the tester cells, with or without activation. The test material was considered inactive in this study.   | 48 FR 12124; 3/23/83<br>Fiche# OTS0508477 |
| Di(2-ethylhexyl) phthalate | 117-81-7 | HEGTOXMUTA<br>Mutagenicity study<br>(Voluntary test)        | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Chinese hamster ovaries (CHO)  | <i>in vitro</i>         | 5.0-80.0 nl/ml  | Not applicable      | DEHP was nontoxic at all concentrations. There were no dose-related increases in mutation frequency.   | 51 FR 6468; 2/24/86<br>Fiche# OTS0509537  |
| Di(2-ethylhexyl) phthalate | 117-81-7 | HEGTOXMUTA<br>Mutagenicity study<br>(Voluntary test)        | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Salmonella typhimurium strains | <i>in vitro</i>         | 0.15-150 µl/plate   | Not applicable      | The test material, DEHP, did not induce genetic activity in any of the tester strains (TA 98, TA 100, TA 1535, TA 1537, TA 1538) in either the absence or presence of metabolic activation.  | 48 FR 12124; 3/23/83<br>Fiche# OTS0508477 |
| Di(2-ethylhexyl) phthalate | 117-81-7 | HEGTOXMUTA<br>Mutagenicity study<br>(Voluntary test)        | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Mouse lymphoma cells L5178Y TK | <i>in vitro</i>         | 7.81-250 nl/ml (nonactivation)<br>7.81-125 nl/ml (activation) | Not applicable      | The test material, DEHP, did not induce increased mutant frequency at the TK locus in the absence or presence of metabolic activation.   | 48 FR 12124; 3/23/83<br>Fiche# OTS0508477 |
| Di(2-ethylhexyl) phthalate | 117-81-7 | HEGTOXMUTA<br>Mutagenicity study<br>(Voluntary test)        | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Chinese hamster ovaries (CHO)  | <i>in vitro</i>         | 5.0-80.0 nl/ml  | Not applicable      | No toxicity was observed with DEHP at any test concentration There were no dose-related increases in mutant frequency.   | 50 FR 1892; 5/3/85<br>Fiche# OTS0508498   |
| Di(2-ethylhexyl) phthalate | 117-81-7 | HESTOX<br>Subchronic toxicity                               | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | rats                           | oral (dietary), 21 days | 0, 0.01, 0.1, 0.6, 1.2, 2.5%                                  | 5 male;<br>5 female | Test animals exposed to 2.5% of di-2-ethylhexyl phthalate (DEHP) lost weight during the first week, and body weights were significantly reduced compared to the controls. There was initial reduction in weight gain in the 1.2% groups. Food consumption was reduced in both sexes at 1.2 and 2.5%. In both sexes, a statistically significant increase in liver weights was observed at 0.6, 1.2, and 2.5%. Histological examinations showed a reduction in cytoplasmic basophilia in livers of male rats exposed to 0.6, 1.2, and 2.5%.   | 51 FR 6468; 2/24/86<br>Fiche# OTS0509537  |
| Di(2-ethylhexyl) adipate   | 123-79-5 | HECTOXTRFM<br>Morphological transformation                  | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | mice, BALB 3T3 cells           | <i>in vitro</i>         | 1.95, 7.81, 31.3, 125, 500 nl/ml                              | Not applicable      | The test material, di(2-ethylhexyl) adipate (DEHA), did not induce an increased number of transformed foci at any of the concentrations tested, with or without activation.  | 48 FR 12124; 3/23/83<br>Fiche# OTS0508477 |
| Di(2-ethylhexyl) adipate   | 123-79-5 | HEGTOXDNAF<br>Unscheduled DNA synthesis<br>(Voluntary test) | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | rat primary hepatocytes        | <i>in vitro</i>         | 5, 10, 25, 50 100, 250, 500, 1000 nl/ml                       | Not applicable      | The test material, DEHA, did not induce significant changes in the nuclear labelling of the tester cells, with or without activation. The test material was considered inactive in this study.   | 48 FR 12124; 3/23/83<br>Fiche# OTS0508477 |
| Di(2-ethylhexyl) adipate   | 123-79-5 | HESTOX<br>Subchronic oral study                             | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | rats                           | diet, 21 days           | 0, 0.6, 1.2, 2.5%   | 5/sex/group         | The rats fed 2.5% lost weight during the first 3 days of treatment and were lighter than the controls. The males fed 2.5% had lower food consumption. The weights and relative weights of the livers of both sexes were increased at 1.2 and 2.5%, and also 0.6% in the females. No reduction in testes weights was observed. There was a dose related reduction of hepatic neutral lipid deposition in all treated rats. Cyanide-insensitive palmitoyl-CoA oxidation was significantly increased in both sexes fed 2.5% and in males fed 1.2%. Lauric acid 11-hydroxylase activity was increased in males (not dose related). The 12-hydroxylase activity was increased in all treated males and 2.5% females. There was a dose related proliferations of peroxisome in all treated groups. | 51 FR 16203; 5/1/86<br>Fiche# OTS0509543  |

## Results of Testing

| Chemical Name      | CAS No.  | Study Code/Type                       | Protocol/Guideline   | Species                                      | Exposure                       | Dose/Concentration   | No. per Group  | Results  | Reference                                  |
|--------------------|----------|---------------------------------------|--|--|--------------------------------|--|----------------|--|--|
| Dimethyl phthalate | 131-11-3 | EEATOX<br>Acute chironomid toxicity   | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Paratanytarsus parthenogenica</i> (midge) | static, 48 hr                  | 0.056-86.3 mg/L (measured)   | Not specified  | Toxic to the midge. The 48-hour LC <sub>50</sub> value is 76 mg/L.   | 49 FR 30114; 7/26/84<br>Fiche# OTS0508488  |
| Dimethyl phthalate | 131-11-3 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Rainbow trout                                | flow-through, 96 hr            | 0.013-100 mg/L (measured)  | Not specified  | Toxic at concentrations below the limit of aqueous solubility. The 96 hr LC <sub>50</sub> value is 56 mg/L.  | 49 FR 18779; 5/2/84<br>Fiche# OTS0508486   |
| Dimethyl phthalate | 131-11-3 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Sheepshead minnow                            | flow-through, 96 hr            | 0.08-60 ppm (measured)   | Not specified  | Toxic to the sheepshead minnow. The 96-hour LC <sub>50</sub> value is 29 mg/L.   | 49 FR 44142; 11/2/84<br>Fiche# OTS0508492  |
| Dimethyl phthalate | 131-11-3 | EEATOX<br>Acute mysid shrimp toxicity | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Mysid shrimp                                 | static, 96 hr                  | 0.056-86.0 mg/L (measured)   | Not specified  | Toxic to the mysid shrimp. The 96-hour LC <sub>50</sub> value is 76 mg/L.  | 49 FR 30114; 7/26/84<br>Fiche# OTS0508488  |
| Dimethyl phthalate | 131-11-3 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Fathead minnow                               | static, 96 hr                  | <0.0037 to 210 mg/L (5 concentrations/test material up to limit of solubility) | Not specified  | Toxic at concentrations below the limit of aqueous solubility. The LC <sub>50</sub> value is 120 mg/L.   | 48 FR 53159; 11/25/83<br>Fiche# OTS0508481 |
| Dimethyl phthalate | 131-11-3 | EEATOX<br>Algae acute toxicity        | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Green alga                                   | static, 6 days                 | 0.05-1409.4 ppm  | Not applicable | Toxic to the test algae. The EC <sub>50</sub> (population growth) value is 145.6 mg/L.   | 50 FR 5421; 2/6/85<br>Fiche# OTS0508496    |
| Dimethyl phthalate | 131-11-3 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Bluegill                                     | static, 96 hr                  | 0.34-1.0 mg/L (measured)   | Not specified  | Toxic to the bluegill. The 96-hour LC <sub>50</sub> value is 67 mg/L.  | 48 FR 53159; 11/25/83<br>Fiche# OTS0508481 |
| Dimethyl phthalate | 131-11-3 | EEATOX<br>Daphnid acute toxicity      | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Daphnia magna</i>                         | static, 48 hr                  | 5 concentrations up to water solubility limits                                 | Not specified  | The 48-hour LC <sub>50</sub> value is >52 mg/L.  | 49 FR 44142; 11/2/84<br>Fiche# OTS0508492  |
| Dimethyl phthalate | 131-11-3 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Fathead minnow                               | flow-through, 96 hr            | 0.026-34 mg/L (measured)   | Not specified  | Toxic to the fathead minnow. The 96-hour LC <sub>50</sub> value is 39 mg/L.  | 48 FR 53159; 11/25/83<br>Fiche# OTS0508481 |
| Dimethyl phthalate | 131-11-3 | EECLIF<br>Fish early life stage       | 797.1600 (modified)  | Rainbow trout ( <i>Oncorhynchus mykiss</i> ) | flow-through, 102 days         | 0, 4.8, 9.0, 15.0, 30.0, 60.0 mg/L (nominal)                                   | 30             | Exposure of embryos, larvae, and juvenile fish to the test substance resulted in a lowest observed effect concentration of 30 mg/L, a no observed effect concentration (NOEC) of 15.0 mg/L, and a maximum acceptable toxicant concentration (MATC) of 16 mg/L. The most sensitive parameter was survival at the conclusion of the test, no rainbow trout survived to hatch at 60 mg/L, and significantly reduced at 30 mg/L. | Fiche# OTS0533141                          |
| Dimethyl phthalate | 131-11-3 | EECTOX<br>Chronic daphnid toxicity    | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Daphnia magna</i>                         | flow-through, 21 days          | 0.015-80 mg/L (measured)   | Not specified  | Toxic to <i>Daphnia magna</i> . Maximum affect test concentration (MATC) was 15 mg/L.  | 50 FR 5421; 2/6/85<br>Fiche# OTS0508496    |
| Dimethyl phthalate | 131-11-3 | EFBDEG<br>Biodegradation study        | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable                               | shake flask, 28 days, CO by GC | 4 mg carbon/equivalent   | Not applicable | Primary biodegradation of 90% or higher and ultimate biodegradation of 55%.  | 48 FR 53159; 11/25/83<br>OTS0508481        |

## Results of Testing

| Chemical Name        | CAS No.    | Study Code/Type                            | Protocol/Guideline   | Species                                      | Exposure  | Dose/Concentration  | No. per Group  | Results   | Reference                                     |
|----------------------|------------|--|--|--|---|---|----------------|---|---|
| Dimethyl phthalate   | 131-11-3   | EFBDEG<br>Biodegradation study             | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable                               | 23° C, 24 hr, CO <sub>2</sub> by GC   | 1 mg/L  | Not applicable | Primary degradation in excess of 90% in 24 hours.   | 49 FR 44142; 11/2/84<br>Fiche# OTS0508490     |
| Dimethyl phthalate   | 131-11-3   | EFCHWSOL<br>Water solubility               | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable                               | deionized water, well and sea water; equilibrate for 24 hr at 25 ± 2° C; analysis by GC | Not specified   | Not applicable | In distilled water, DMP had a solubility of 4000 ± 60 mg/L in well water, 3960 ± 230 mg/L, and for sea water 3160 ± 160 mg/L.   | 48 FR 34119; 7/27/83<br>Fiche# OTS0508479     |
| Dimethyl phthalate   | 131-11-3   | EFPCHEPART<br>Octanol/water partition      | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable                               | octanol/deionized water at 25 °C, analysis by GC  | 10 <sup>-2</sup> M  | Not applicable | The log Kow value with standard errors was 1.47 ± 0.086.  | 49 FR 44142; 11/2/84<br>Fiche# OTS0508491     |
| Dimethyl phthalate   | 131-11-3   | EFPCHEVPRE<br>Vapor Pressure               | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable                               | 25 °C, analysis by GC   | Not specified   | Not applicable | Vapor pressure = 2.2 x 10 <sup>-1</sup> .   | 49 FR 44124; 11/2/84<br>Fiche# OTS0508490     |
| Dimethyl phthalate   | 131-11-3   | HECTOXTRFM<br>Morphological transformation | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | mice, BALB 3T3 cells                         | <i>in vitro</i>   | 62.1-931.6 nl/ml  | Not applicable | The test material, dimethyl phthalate (DMP), did not induce significant increases in transformed foci frequency, with or without activation.  | 50 FR 46699;<br>11/12/85<br>Fiche# OTS0509537 |
| Dimethyl phthalate   | 131-11-3   | HEGTOXMUTA<br>Mutagenicity study           | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | mouse, L5178Y cells                          | <i>in vitro</i>   | 9.77, 19.5, 39.1, 78.1, 156, 313, 625, 1250, 2500, 5000 nl/ml | Not applicable | The test material, DMP, in the absence of metabolic activation was weakly toxic at 625 nl/ml after 48 hours. In the presence of metabolic activation, the test material was lethal at 1250 nl/ml. | 51 FR 6468; 2/24/86<br>Fiche# OTS0509537      |
| Diisooctyl phthalate | 27554-26-3 | EEATOX<br>Acute fish toxicity              | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Rainbow trout                                | flow-through, 96 hr   | 0.013-100 mg/L (measured)                                     | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 49 FR 18779; 5/2/84<br>Fiche# OTS0508486      |
| Diisooctyl phthalate | 27554-26-3 | EEATOX<br>Acute fish toxicity              | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Sheepshead minnow                            | flow-through, 96 hr   | 0.08-60 ppm (measured)  | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 49 FR 44142; 11/2/84<br>Fiche# OTS0508492     |
| Diisooctyl phthalate | 27554-26-3 | EEATOX<br>Acute fish toxicity              | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Bluegill                                     | static, 96 hr   | 0.34-1.0 mg/L (measured)                                      | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0508481 |
| Diisooctyl phthalate | 27554-26-3 | EEATOX<br>Acute chironomid toxicity        | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Paratanytarsus parthenogenica</i> (midge) | static, 48 hr   | 0.056-86.3 mg/L (measured)                                    | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 49 FR 30114; 7/26/84<br>Fiche# OTS0508488     |
| Diisooctyl phthalate | 27554-26-3 | EEATOX<br>Acute fish toxicity              | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Fathead minnow                               | flow-through, 96 hr   | 0.026-34 mg/L (measured)                                      | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0508481 |
| Diisooctyl phthalate | 27554-26-3 | EEATOX<br>Algae acute toxicity             | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Green alga                                   | static, 6 days  | 0.05-1409.4 ppm   | Not applicable | No acute toxicity below the limit of aqueous solubility.  | 50 FR 5421; 2/6/85<br>Fiche# OTS0508496       |

## Results of Testing

| Chemical Name        | CAS No.    | Study Code/Type                       | Protocol/Guideline   | Species                                      | Exposure  | Dose/Concentration   | No. per Group  | Results   | Reference                                     |
|----------------------|------------|---------------------------------------|--|--|---|--|----------------|---|---|
| Diisooctyl phthalate | 27554-26-3 | EEATOX<br>Acute mysid shrimp toxicity | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Mysid shrimp                                 | static, 96 hr   | 0.056-86.0 mg/L<br>(measured)  | Not specified  | No acute toxicity below the limit of aqueous solubility.                    | 49 FR 30114; 7/26/84<br>Fiche# OTS0508488     |
| Diisooctyl phthalate | 27554-26-3 | EEATOX<br>Daphnid acute toxicity      | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Daphnia magna</i>                         | static, 48 hr   | 5 concentrations up to water solubility limits                                 | Not specified  | The 48-hour LC <sub>50</sub> value is >0.22 mg/L.                           | 49 FR 44142; 11/2/84<br>Fiche# OTS0508492     |
| Diisooctyl phthalate | 27554-26-3 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Fathead minnow                               | static, 96 hr   | <0.0037 to 210 mg/L (5 concentrations/test material up to limit of solubility) | Not specified  | No acute toxicity below the limit of aqueous solubility.                    | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0508481 |
| Diisooctyl phthalate | 27554-26-3 | EECTOX<br>Chronic daphnid toxicity    | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Daphnia magna</i>                         | flow-through, 21 days   | 0.015-80 mg/L<br>(measured)  | Not specified  | Non-toxic.  | 50 FR 5421; 2/6/85<br>Fiche# OTS0508496       |
| Diisooctyl phthalate | 27554-26-3 | EFBDEG<br>Biodegradation study        | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable                               | 23° C, 24 hr, CO <sub>2</sub> by GC                                 | 1 mg/L   | Not applicable | Exhibited at least 50% primary degradation in 24 hours.                     | 49 FR 44142; 11/2/84<br>Fiche# OTS0508490     |
| Diisooctyl phthalate | 27554-26-3 | EFBDEG<br>Biodegradation study        | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable                               | shake flask, 28 days, CO by GC                                      | 4 mg carbon/equivalent   | Not applicable | Primary biodegradation of 90% or higher and ultimate biodegradation of 55%. | 48 FR 53159;<br>11/25/83<br>OTS0508481        |
| Diisooctyl phthalate | 27554-26-3 | EFCHEWSOL<br>Water solubility         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable                               | deionized water; equilibrate for 24 hr at 25 ± 2° C; analysis by GC | Not specified  | Not applicable | Solubility in distilled water = 0.09 ± 0.01 mg/L.                           | 48 FR 34119; 7/27/83<br>Fiche# OTS0508479     |
| Diisooctyl phthalate | 27554-26-3 | EFPCHEVPRE<br>Vapor Pressure          | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable                               | 25 °C, analysis by GC   | Not specified  | Not applicable | Vapor pressure = 7.4 x 10 <sup>-4</sup> .                                   | 49 FR 44124; 11/2/84<br>Fiche# OTS0508490     |
| Diundecyl phthalate  | 3648-20-2  | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Sheepshead minnow                            | flow-through, 96 hr   | 0.08-60 ppm (measured)   | Not specified  | No acute toxicity below the limit of aqueous solubility.                    | 49 FR 44142; 11/2/84<br>Fiche# OTS0508492     |
| Diundecyl phthalate  | 3648-20-2  | EEATOX<br>Acute chironomid toxicity   | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Paratanytarsus parthenogenica</i> (midge) | static, 48 hr   | 0.056-86.3 mg/L<br>(measured)  | Not specified  | No acute toxicity below the limit of aqueous solubility.                    | 49 FR 30114; 7/26/84<br>Fiche# OTS0508488     |
| Diundecyl phthalate  | 3648-20-2  | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Bluegill                                     | static, 96 hr   | 0.34-1.0 mg/L<br>(measured)  | Not specified  | No acute toxicity below the limit of aqueous solubility.                    | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0508481 |
| Diundecyl phthalate  | 3648-20-2  | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Fathead minnow                               | static, 96 hr   | <0.0037 to 210 mg/L (5 concentrations/test material up to limit of solubility) | Not specified  | No acute toxicity below the limit of aqueous solubility.                    | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0508481 |
| Diundecyl phthalate  | 3648-20-2  | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Fathead minnow                               | flow-through, 96 hr   | 0.026-34 mg/L<br>(measured)  | Not specified  | No acute toxicity below the limit of aqueous solubility.                    | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0508481 |



## Results of Testing

| Chemical Name               | CAS No.   | Study Code/Type   | Protocol/Guideline   | Species              | Exposure  | Dose/Concentration  | No. per Group  | Results  | Reference                                     |
|-----------------------------|-----------|---|--|----------------------|---|---|----------------|--|---|
| Diundecyl phthalate         | 3648-20-2 | EEATOX<br>Daphnid acute toxicity                            | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Daphnia magna</i> | static, 48 hr   | 5 concentrations up to water solubility limits                      | Not specified  | The 48-hour LC <sub>50</sub> value is >0.22 mg/L.  | 49 FR 44142; 11/2/84<br>Fiche# OTS0508492     |
| Diundecyl phthalate         | 3648-20-2 | EEATOX<br>Acute fish toxicity                               | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Rainbow trout        | flow-through, 96 hr   | 0.013-100 mg/L (measured)   | Not specified  | No acute toxicity below the limit of aqueous solubility.   | 49 FR 18779; 5/2/84<br>Fiche# OTS0508486      |
| Diundecyl phthalate         | 3648-20-2 | EEATOX<br>Acute mysid shrimp toxicity                       | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Mysid shrimp         | static, 96 hr   | 0.056-86.0 mg/L (measured)  | Not specified  | No acute toxicity below the limit of aqueous solubility.   | 49 FR 30114; 7/26/84<br>Fiche# OTS0508488     |
| Diundecyl phthalate         | 3648-20-2 | EEATOX<br>Algae acute toxicity                              | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Green alga           | static, 6 days  | 0.05-1409.4 ppm   | Not applicable | No acute toxicity below the limit of aqueous solubility.   | 50 FR 5421; 2/6/85<br>Fiche# OTS0508496       |
| Diundecyl phthalate         | 3648-20-2 | EECTO<br>Chronic daphnid toxicity                           | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Daphnia magna</i> | flow-through, 21 days   | 0.015-80 mg/L (measured)  | Not specified  | Non-toxic.   | 50 FR 5421; 2/6/85<br>Fiche# OTS0508496       |
| Diundecyl phthalate         | 3648-20-2 | EFBDEG<br>Biodegradation study                              | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable       | shake flask, 28 d, CO by GC   | 4 mg carbon/equivalent  | Not applicable | Primary biodegradation of 90% or higher and ultimate biodegradation of 55%.  | 48 FR 53159;<br>11/25/83<br>OTS0508481        |
| Diundecyl phthalate         | 3648-20-2 | EFCHWSOL<br>Water solubility                                | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable       | deionized water; equilibrate for 24 hr at 25 ± 2 °C; analysis by GC | Not specified   | Not applicable | Solubility in distilled water = <0.03 mg/L.  | 48 FR 34119; 7/27/83<br>Fiche# OTS0508479     |
| Diundecyl phthalate         | 3648-20-2 | HECTOXTRFM<br>Morphological transformation                  | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | mice, BALB 3T3 cells | <i>in vitro</i>   | 4000-100,000 nl/ml  | Not applicable | The test material, diundecyl phthalate (DUP), was nontoxic, and did not induce a significantly increased frequency in transformed foci, with or without activation.  | 50 FR 46699;<br>11/12/85<br>Fiche# OTS0509537 |
| Diundecyl phthalate         | 3648-20-2 | HEGTOXMUTA<br>Mutagenicity study                            | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | mouse, L5178Y cells  | <i>in vitro</i>   | 2000 - 10,000 nl/ml (nonactivation); 1000 - 8000 nl/ml (activation) | Not applicable | The test substance did not induce any significant increases in the mutant frequency at the thymidine kinase (TK) locus, with or without activation.  | 51 FR 39799;<br>10/31/86<br>Fiche# OTS0510528 |
| Diundecyl phthalate         | 3648-20-2 | HEGTOXMUTA<br>Mutagenicity study                            | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | mouse, L5178Y cells  | <i>in vitro</i>   | 9.77, 19.5, 39.1, 78.1, 156, 313, 625, 1250, 2500, 5000 nl/ml       | Not applicable | In the absence and presence of metabolic activation, the test material, DUP, showed a concentration-related increase in toxicity.  | 51 FR 6468; 2/24/86<br>Fiche# OTS0509537      |
| Mono-2-ethylhexyl phthalate | 4376-20-9 | HECTOXTRFM<br>Morphological transformation (Voluntary test) | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | mice, BALB 3T3 cells | <i>in vitro</i>   | 25, 50, 75, 100, 125 nl/ml  | Not applicable | The test material, mono-2-ethylhexyl phthalate (MEHP), did not induce an increased number of transformed foci at any of the concentrations tested, with or with out activation.  | 48 FR 12124; 3/23/83<br>Fiche# OTS0508477     |
| Mono-2-ethylhexyl phthalate | 4376-20-9 | HEGTOXCHRM<br>Chromosomal study (Voluntary test)            | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | mice                 | intraperitoneal (i.p.), single dose, 2-doses; 24 hr apart           | 125 mg/kg/day   | Not specified  | The test material, MEHP, induced a significant increase in micronucleated polychromatic erythrocytes of female test animals in the repeated test group. Males in the acute and repeated treatment groups had no significant increases in the percent of micronucleated polychromatic erythrocytes when compared to the controls. | 48 FR 12124; 3/23/83<br>Fiche# OTS0508477     |

## Results of Testing

| Chemical Name                        | CAS No.    | Study Code/Type                                   | Protocol/Guideline   | Species                                      | Exposure                            | Dose/Concentration  | No. per Group  | Results   | Reference                                  |
|--------------------------------------|------------|---|--|--|-------------------------------------|---|----------------|---|--|
| Mono-2-ethylhexyl phthalate          | 4376-20-9  | HEGTOXMUTA<br>Mutagenicity study                  | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Chinese hamster ovaries (CHO)                | <i>in vitro</i>                     | 50-350 nl/ml (nonactivation)<br>20-200 nl/ml (activation)       | Not applicable | The test material, MEHP, was highly toxic and/or lethal at concentrations above 350 nl/ml without activation and above 200 nl/ml with activation. The remaining concentrations did not induce increases in mutant frequency, and none were toxic.           | 50 FR 1892; 5/3/85<br>Fiche# OTS0508498    |
| Mono-2-ethylhexyl phthalate          | 4376-20-9  | HEGTOXMUTA<br>Mutagenicity study (Voluntary test) | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Salmonella typhimurium strains               | <i>in vitro</i>                     | 1.03-1030 µg/plate  | Not applicable | The test material, MEHP, did not induce genetic activity in any of the tested strains (TA 98, TA 100, TA 1535, TA 1537, TA 1538) in either the absence or presence of metabolic activation.   | 48 FR 12124; 3/23/83<br>Fiche# OTS0508477  |
| Di(heptyl, nonyl, undecyl) phthalate | 68515-42-4 | EEATOX<br>Acute chironomid toxicity               | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Paratanytarsus parthenogenica</i> (midge) | static, 48 hr                       | 0.056-86.3 mg/L (measured)                                      | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 49 FR 30114; 7/26/84<br>Fiche# OTS0508488  |
| Di(heptyl, nonyl, undecyl) phthalate | 68515-42-4 | EEATOX<br>Acute fish toxicity                     | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Bluegill                                     | static, 96 hr                       | 0.34-1.0 mg/L (measured)  | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 48 FR 53159; 11/25/83<br>Fiche# OTS0508481 |
| Di(heptyl, nonyl, undecyl) phthalate | 68515-42-4 | EEATOX<br>Daphnid acute toxicity                  | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Daphnia magna</i>                         | static, 48 hr                       | 5 concentrations up to water solubility limits                  | Not specified  | The 48-hour LC <sub>50</sub> value is >0.062 mg/L.  | 49 FR 44142; 11/2/84<br>Fiche# OTS0508492  |
| Di(heptyl, nonyl, undecyl) phthalate | 68515-42-4 | EECLIF<br>Fish early life stage                   | 797.1600 (modified)  | Rainbow trout ( <i>Oncorhynchus mykiss</i> ) | flow-through, 152 days              | 0, 0.38, 0.075, 0.15, 0.30, 0.60 mg/L (nominal)                 | 20             | The results indicate that embryo hatchability, fry survival, standard length and blotted wet weight was not significantly affected at any concentration. No statistical evidence of treatment-related effects were observed during this study at 0.60 mg/L. | Fiche# OTS0533140                          |
| Di(heptyl, nonyl, undecyl) phthalate | 68515-42-4 | EECTOX<br>Chronic daphnid toxicity                | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Daphnia magna</i>                         | flow-through, 21 days               | 0.015-80 mg/L (measured)  | Not specified  | Non-toxic.  | 50 FR 5421; 2/6/85<br>Fiche# OTS0508496    |
| Di(heptyl, nonyl, undecyl) phthalate | 68515-42-4 | EFBDEG<br>Biodegradation study                    | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable                               | 23° C, 24 hr, CO <sub>2</sub> by GC | 1 mg/L  | Not applicable | Exhibited at least 50% primary degradation in 24 hours.   | 49 FR 44142; 11/2/84<br>Fiche# OTS0508490  |
| Di(heptyl, nonyl, undecyl) phthalate | 68515-42-4 | HECTOXRFRM<br>Morphological transformation        | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | mice, BALB 3T3 cells                         | <i>in vitro</i>                     | 60-6000 nl/ml   | Not applicable | The test material, di(heptyl, nonyl, undecyl) phthalate (711P), did not induce a significant number of transformed foci over the concentration range with or without activation.  | 50 FR 46699; 11/12/85<br>Fiche# OTS0509537 |
| Di(heptyl, nonyl, undecyl) phthalate | 68515-42-4 | HEGTOXMUTA<br>Mutagenicity study                  | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | mouse, L5178Y cells                          | <i>in vitro</i>                     | 9.77, 19.5, 39.1, 78.1, 156, 313, 625, 1250, 2500, 5000 nl/ml   | Not applicable | In the absence of metabolic activation, the test material, was highly toxic at 2500 and 5000 nl/ml. In the presence of metabolic activation, the test material was lethal at 5000 nl/ml, and the 1250 and 2500 nl/ml media were highly toxic.               | 51 FR 6468; 2/24/86<br>Fiche# OTS0509537   |
| Di(heptyl, nonyl, undecyl) phthalate | 68515-42-4 | HEGTOXMUTA<br>Mutagenicity study                  | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | mouse, L5178Y cells                          | <i>in vitro</i>                     | 750 - 6000 nl/ml (nonactivation); 125 - 1500 nl/ml (activation) | Not applicable | The test substance did not induce any significant increases in the mutant frequency at the thymidine kinase (TK) locus, with or without activation.   | 51 FR 39799; 10/31/86<br>Fiche# OTS0510528 |

## Results of Testing

| Chemical Name                        | CAS No.    | Study Code/Type                       | Protocol/Guideline   | Species                                      | Exposure            | Dose/Concentration   | No. per Group  | Results   | Reference                                  |
|--------------------------------------|------------|---------------------------------------|--|--|---------------------|--|----------------|---|--|
| Di(heptyl, nonyl, undecyl) phthalate | 68515-42-4 | HESTOX<br>Subchronic oral study       | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | rats   | diet, 21 days       | 0, 0.3, 1.2, 2.5%  | 5/sex/group    | The treatment decreased body weight gain (mid- and high dose males), food intake (high-dose males), and testis weights (high-dose males) and increased relative liver (mid- and high-dose, both sexes) and kidney weights (mid- and high-dose females, and high-dose males). In livers of treated rats, vacuolization of hepatocytes with cell necrosis (mid- and high-dose males), peroxisomes (high-dose males), cyanide-insensitive palmitoyl-CoA oxidation (mid- and high-dose, both sexes), and lauric acid 12- hydroxylase (all levels, both sexes) were all increased and cytoplasmic basophilia was reduced (high-dose females). There was a treatment-related decrease in periportal lipids in females, and serum triglyceride and cholesterol levels were reduced in all treated males. | 51 FR 16203; 5/1/86<br>Fiche# OTS0509543   |
| Ditridecyl phthalate                 | 68515-47-9 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Fathead minnow                               | flow-through, 96 hr | 0.026-34 mg/L (measured)   | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 48 FR 53159; 11/25/83<br>Fiche# OTS0508481 |
| Ditridecyl phthalate                 | 68515-47-9 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Rainbow trout                                | flow-through, 96 hr | 0.013-100 mg/L (measured)  | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 49 FR 18779; 5/2/84<br>Fiche# OTS0508486   |
| Ditridecyl phthalate                 | 68515-47-9 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Fathead minnow                               | static, 96 hr       | <0.0037 to 210 mg/L (5 concentrations/test material up to limit of solubility) | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 48 FR 53159; 11/25/83<br>Fiche# OTS0508481 |
| Ditridecyl phthalate                 | 68515-47-9 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Sheepshead minnow                            | flow-through, 96 hr | 0.08-60 ppm (measured)   | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 49 FR 44142; 11/2/84<br>Fiche# OTS0508492  |
| Ditridecyl phthalate                 | 68515-47-9 | EEATOX<br>Acute mysid shrimp toxicity | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Mysid shrimp                                 | static, 96 hr       | 0.056-86.0 mg/L (measured)   | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 49 FR 30114; 7/26/84<br>Fiche# OTS0508488  |
| Ditridecyl phthalate                 | 68515-47-9 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Bluegill                                     | static, 96 hr       | 0.34-1.0 mg/L (measured)   | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 48 FR 53159; 11/25/83<br>Fiche# OTS0508481 |
| Ditridecyl phthalate                 | 68515-47-9 | EEATOX<br>Daphnid acute toxicity      | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Daphnia magna</i>                         | static, 48 hr       | 5 concentrations up to water solubility limits                                 | Not specified  | The 48-hour LC <sub>50</sub> value is >0.68 mg/L.   | 49 FR 44142; 11/2/84<br>Fiche# OTS0508492  |
| Ditridecyl phthalate                 | 68515-47-9 | EEATOX<br>Algae acute toxicity        | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Green alga                                   | static, 6 days      | 0.05-1409.4 ppm  | Not applicable | No acute toxicity below the limit of aqueous solubility.  | 50 FR 5421; 2/6/85<br>Fiche# OTS0508496    |
| Ditridecyl phthalate                 | 68515-47-9 | EEATOX<br>Acute chironomid toxicity   | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Paratanytarsus parthenogenica</i> (midge) | static, 48 hr       | 0.056-86.3 mg/L (measured)   | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 49 FR 30114; 7/26/84<br>Fiche# OTS0508488  |

## Results of Testing

| Chemical Name        | CAS No.    | Study Code/Type                        | Protocol/Guideline   | Species                                      | Exposure   | Dose/Concentration   | No. per Group  | Results  | Reference                                     |
|----------------------|------------|--|--|--|--|--|----------------|--|---|
| Ditridecyl phthalate | 68515-47-9 | EECTOX<br>Chronic daphnid toxicity     | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Daphnia magna</i>                         | flow-through, 21 days  | 0.015-80 mg/L (measured)   | Not specified  | Non-toxic.   | 50 FR 5421; 2/6/85<br>Fiche# OTS0508496       |
| Ditridecyl phthalate | 68515-47-9 | EFBDEG<br>Biodegradation study         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable                               | 23° C, 24 hr, CO <sub>2</sub> by GC                                | 1 mg/L   | Not applicable | Exhibited at least 50% primary degradation in 24 hours.  | 49 FR 44142; 11/2/84<br>Fiche# OTS0508490     |
| Ditridecyl phthalate | 68515-47-9 | EFBDEG<br>Biodegradation study         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable                               | shake flask, 28 d, CO by GC  | 4 mg carbon/equivalent   | Not applicable | Primary biodegradation of 90% or higher and ultimate biodegradation of 55%.  | 48 FR 53159;<br>11/25/83<br>OTS508481         |
| Ditridecyl phthalate | 68515-47-9 | EFCHWSOL<br>Water solubility           | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable                               | deionized water; equilibrate for 24 h at 25 ± 2° C; analysis by GC | Not specified  | Not applicable | Solubility in distilled water = 1.19 ± 0.19 mg/L.  | 48 FR 34119; 7/27/83<br>Fiche# OTS0508479     |
| Ditridecyl phthalate | 68515-47-9 | EFTSPT<br>Sediment adsorption isotherm | 796.2750 (modified)  | Not applicable                               | Not specified.   | 0.003, 0.012, 0.024, 0.036, 0.049, 0.073 ml aliquots                           | Not applicable | The mean percents adsorbed to sediments EPA 8, EPA 18, EPA 21 were 80.3%, 82.5%, and 81.1%, respectively. Correlation coefficients were 0.928, 0.939, and 0.963 for sediments EPA 8, EPA 18, and EPA 21, respectively. HPLC analysis of aqueous adsorption phases and sediment extracts demonstrated stability. The mean C14-mass balance accountabilities were 99.5%, 103%, and 102% for sediments EPA 8, EPA 18, EPA 21, respectively. | 56 FR 42623; 8/28/91<br>Fiche# OTS0533017     |
| Diisononyl phthalate | 68515-48-0 | EEATOX<br>Acute fish toxicity          | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Sheepshead minnow                            | flow-through, 96 hr  | 0.08-60 ppm (measured)   | Not specified  | No acute toxicity below the limit of aqueous solubility.   | 49 FR 44142; 11/2/84<br>Fiche# OTS0508492     |
| Diisononyl phthalate | 68515-48-0 | EEATOX<br>Acute chironomid toxicity    | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Paratanytarsus parthenogenica</i> (midge) | static, 48 hr  | 0.056-86.3 mg/L (measured)   | Not specified  | No acute toxicity below the limit of aqueous solubility.   | 49 FR 30114; 7/26/84<br>Fiche# OTS0508488     |
| Diisononyl phthalate | 68515-48-0 | EEATOX<br>Acute fish toxicity          | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Bluegill                                     | static, 96 hr  | 0.34-1.0 mg/L (measured)   | Not specified  | No acute toxicity below the limit of aqueous solubility.   | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0508481 |
| Diisononyl phthalate | 68515-48-0 | EEATOX<br>Algae acute toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Green alga                                   | static, 6 days   | 0.05-1409.4 ppm  | Not applicable | No acute toxicity below the limit of aqueous solubility.   | 50 FR 5421; 2/6/85<br>Fiche# OTS0508496       |
| Diisononyl phthalate | 68515-48-0 | EEATOX<br>Acute fish toxicity          | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Fathead minnow                               | flow-through, 96 hr  | 0.026-34 mg/L (measured)   | Not specified  | No acute toxicity below the limit of aqueous solubility.   | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0508481 |
| Diisononyl phthalate | 68515-48-0 | EEATOX<br>Acute fish toxicity          | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Fathead minnow                               | static, 96 hr  | <0.0037 to 210 mg/L (5 concentrations/test material up to limit of solubility) | Not specified  | No acute toxicity below the limit of aqueous solubility.   | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0508481 |
| Diisononyl phthalate | 68515-48-0 | EEATOX<br>Acute fish toxicity          | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Rainbow trout                                | flow-through, 96 hr  | 0.013-100 mg/L (measured)  | Not specified  | No acute toxicity below the limit of aqueous solubility.   | 49 FR 18779; 5/2/84<br>Fiche# OTS0508486      |

## Results of Testing

| Chemical Name        | CAS No.    | Study Code/Type                            | Protocol/Guideline   | Species              | Exposure  | Dose/Concentration   | No. per Group  | Results  | Reference                                     |
|----------------------|------------|--|--|----------------------|---|--|----------------|--|---|
| Diisononyl phthalate | 68515-48-0 | EEATOX<br>Daphnid acute toxicity           | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Daphnia magna</i> | static, 48 hr   | 5 concentrations up to water solubility limits                   | Not specified  | The 48-hour LC <sub>50</sub> value is >0.086 mg/L.   | 49 FR 44142; 11/2/84<br>Fiche# OTS0508492     |
| Diisononyl phthalate | 68515-48-0 | EEATOX<br>Acute mysid shrimp toxicity      | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Mysid shrimp         | static, 96 hr   | 0.056-86.0 mg/L (measured)                                       | Not specified  | No acute toxicity below the limit of aqueous solubility.   | 49 FR 30114; 7/26/84<br>Fiche# OTS0508488     |
| Diisononyl phthalate | 68515-48-0 | EECTOX<br>Chronic daphnid toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Daphnia magna</i> | flow-through, 21 days   | 0.015-80 mg/L (measured)   | Not specified  | Non-toxic.   | 50 FR 5421; 2/6/85<br>Fiche# OTS0508496       |
| Diisononyl phthalate | 68515-48-0 | EFBDEG<br>Biodegradation study             | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable       | 23° C, 24 hr, CO <sub>2</sub> by GC                                 | 1 mg/L   | Not applicable | Exhibited at least 50% primary degradation in 24 hours.  | 49 FR 44142; 11/2/84<br>Fiche# OTS0508490     |
| Diisononyl phthalate | 68515-48-0 | EFBDEG<br>Biodegradation study             | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable       | shake flask, 28 d, CO by GC   | 4 mg carbon/equivalent   | Not applicable | Primary biodegradation of 90% or higher and ultimate biodegradation of 55%.  | 48 FR 53159;<br>11/25/83<br>OTS508481         |
| Diisononyl phthalate | 68515-48-0 | EFCHWSOL<br>Water solubility               | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable       | deionized water; equilibrate for 24 hr at 25 ± 2° C; analysis by GC | Not specified  | Not applicable | Solubility in distilled water = 0.224 ± 0.1 mg/L.  | 48 FR 34119; 7/27/83<br>Fiche# OTS0508479     |
| Diisononyl phthalate | 68515-48-0 | EFPCHEVPRE<br>Vapor Pressure               | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable       | 25 °C, analysis by GC   | Not specified  | Not applicable | Vapor pressure = 7.2 x 10 <sup>-5</sup> .  | 49 FR 44124; 11/2/84<br>Fiche# OTS0508490     |
| Diisononyl phthalate | 68515-48-0 | HECTOXTRFM<br>Morphological transformation | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | mice, BALB 3T3 cells | <i>in vitro</i>   | 125-3750 nl/ml   | Not applicable | The test material, diisonyl phthalate (DINP), was nontoxic and did not induce an increased frequency of transformed foci at any of the test concentrations, with or without activation.  | 50 FR 46699;<br>11/12/85<br>Fiche# OTS0509537 |
| Diisononyl phthalate | 68515-48-0 | HEGTOXMUTA<br>Mutagenicity study           | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | mouse, L5178Y cells  | <i>in vitro</i>   | 1500 - 8000 nl/ml (nonactivation); 500 - 6000 nl/ml (activation) | Not applicable | The test substance did not induce any significant increases in the mutant frequency at the thymidine kinase (TK) locus, with or without activation.  | 51 FR 39799;<br>10/31/86<br>Fiche# OTS0510528 |
| Diisononyl phthalate | 68515-48-0 | HEGTOXMUTA<br>Mutagenicity study           | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | mouse, L5178Y cells  | <i>in vitro</i>   | 9.77, 19.5, 39.1, 78.1, 156, 313, 625, 1250, 2500, 5000 nl/ml    | Not applicable | In the absence of metabolic activation, the test material, DINP, was soluble from 9.77 to 313 nl/ml, but higher concentrations contained small oil droplets. At 1250 ml/ml treatment was moderately toxic. In the presence of metabolic activation, the test material was slightly more toxic than non-activation. | 51 FR 6468; 2/24/86<br>Fiche# OTS0509537      |

## Results of Testing

| Chemical Name        | CAS No.    | Study Code/Type                       | Protocol/Guideline   | Species  | Exposure            | Dose/Concentration   | No. per Group | Results   | Reference                                     |
|----------------------|------------|---------------------------------------|--|--|---------------------|--|---------------|---|---|
| Diisononyl phthalate | 68515-48-0 | HESTOX<br>Subchronic oral study       | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | rats   | diet, 21 days       | 0, 0.6, 1.2, 2.5%  | 5/sex/group   | Decreased body weights were evident at 1.2 and 2.5% in both sexes. Early in treatment food intakes were reduced in both sexes at 2.5% and males at 1.2%. The weights and relative weights of the livers and kidneys were significantly increased in all treated groups. The relative testis weights were higher than control at 2.5%. No treatment related effects were seen histologically. There was a reduction in hepatocyte cytoplasmic basophilia at 1.2 and 2.5%. Lower periportal lipid levels were seen in all treated animals (not dose related). Serum triglycerides and cholesterol levels were reduced in all treated males, and serum cholesterol levels were reduced in treated females, while serum triglycerides were raised. Treatment at 2.5% produced a very marked increase in peroxisomes in males and a marked increase in females. Cyanide-insensitive palmitoyl-CoA was increased in all treated groups, significantly in the two higher doses (dose related). There was a dose-related increase in the 11- and 12- hydroxylation of lauric acid, the males being more sensitive, and total hepatic protein levels were increased. | 51 FR 16203; 5/1/86<br>Fiche# OTS0509543      |
| Diisodecyl phthalate | 68515-49-1 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Bluegill   | static, 96 hr       | 0.34-1.0 mg/L<br>(measured)  | Not specified | No acute toxicity below the limit of aqueous solubility.  | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0508481 |
| Diisodecyl phthalate | 68515-49-1 | EEATOX<br>Acute chironomid toxicity   | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Paratanytarsus partheno-genica</i><br>(midge) | static, 48 hr       | 0.056-86.3 mg/L<br>(measured)  | Not specified | No acute toxicity below the limit of aqueous solubility.  | 49 FR 30114; 7/26/84<br>Fiche# OTS0508488     |
| Diisodecyl phthalate | 68515-49-1 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Fathead minnow                                   | static, 96 hr       | <0.0037 to 210 mg/L (5 concentrations/test material up to limit of solubility) | Not specified | No acute toxicity below the limit of aqueous solubility.  | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0508481 |
| Diisodecyl phthalate | 68515-49-1 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Sheepshead minnow                                | flow-through, 96 hr | 0.08-60 ppm (measured)   | Not specified | No acute toxicity below the limit of aqueous solubility.  | 49 FR 44142; 11/2/84<br>Fiche# OTS0508492     |
| Diisodecyl phthalate | 68515-49-1 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Rainbow trout                                    | flow-through, 96 hr | 0.013-100 mg/L<br>(measured)   | Not specified | No acute toxicity below the limit of aqueous solubility.  | 49 FR 18779; 5/2/84<br>Fiche# OTS0508486      |
| Diisodecyl phthalate | 68515-49-1 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Fathead minnow                                   | flow-through, 96 hr | 0.026-34 mg/L<br>(measured)  | Not specified | No acute toxicity below the limit of aqueous solubility.  | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0508481 |
| Diisodecyl phthalate | 68515-49-1 | EEATOX<br>Acute mysid shrimp toxicity | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Mysid shrimp                                     | static, 96 hr       | 0.056-86.0 mg/L<br>(measured)  | Not specified | No acute toxicity below the limit of aqueous solubility.  | 49 FR 30114; 7/26/84<br>Fiche# OTS0508488     |
| Diisodecyl phthalate | 68515-49-1 | EEATOX<br>Daphnid acute toxicity      | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Daphnia magna</i>                             | static, 48 hr       | 5 concentrations up to water solubility limits                                 | Not specified | The 48-hour LC <sub>50</sub> value is >0.18 mg/L.   | 49 FR 44142; 11/2/84<br>Fiche# OTS0508492     |

## Results of Testing

| Chemical Name        | CAS No.    | Study Code/Type                            | Protocol/Guideline   | Species              | Exposure  | Dose/Concentration  | No. per Group  | Results   | Reference                                     |
|----------------------|------------|--|--|----------------------|---|---|----------------|---|---|
| Diisodecyl phthalate | 68515-49-1 | EEATOX<br>Algae acute toxicity             | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Green alga           | static, 6 days  | 0.05-1409.4 ppm   | Not applicable | No acute toxicity below the limit of aqueous solubility.  | 50 FR 5421; 2/6/85<br>Fiche# OTS0508496       |
| Diisodecyl phthalate | 68515-49-1 | EECTOX<br>Chronic daphnid toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Daphnia magna</i> | flow-through, 21 days   | 0.015-80 mg/L<br>(measured)   | Not specified  | Non-toxic.  | 50 FR 5421; 2/6/85<br>Fiche# OTS0508496       |
| Diisodecyl phthalate | 68515-49-1 | EFBDEG<br>Biodegradation study             | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable       | shake flask, 28 days,<br>CO by GC   | 4 mg carbon/equivalent  | Not applicable | Primary biodegradation of 90% or higher and ultimate biodegradation of 55%.   | 48 FR 53159;<br>11/25/83<br>OTS508481         |
| Diisodecyl phthalate | 68515-49-1 | EFBDEG<br>Biodegradation study             | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable       | 23° C, 24 hr, CO <sub>2</sub> by GC   | 1 mg/L  | Not applicable | Exhibited at least 50% primary degradation in 24 hours.   | 49 FR 44142; 11/2/84<br>Fiche# OTS0508490     |
| Diisodecyl phthalate | 68515-49-1 | EFCHWSOL<br>Water solubility               | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable       | deionized water;<br>equilibrate for<br>24 h at 25 ± 2° C;<br>analysis by GC | Not specified   | Not applicable | Solubility in distilled water = <1 mg/L.  | 48 FR 34119; 7/27/83<br>Fiche# OTS0508479     |
| Diisodecyl phthalate | 68515-49-1 | Sediment adsorption isotherm               | 796.2750 (modified)  | Not applicable       | Not specified   | 0.010, 0.049, 0.097,<br>0.146, 0.194, 0.291 ml<br>aliquots            | Not applicable | The mean percents adsorbed to sediments EPA 8, EPA 18, EPA 21 was 77.0%, 85.8%, and 81.5%, respectively. Correlation coefficients were 0.9430, 0.9647, and 0.9650 for sediments EPA 8, EPA 18, and EPA 21, respectively. HPLC analysis of aqueous adsorption phases and sediment extracts demonstrated stability. The mean C14-mass balance accountability was 103%, 99.2%, and 101% for sediments EPA 8, EPA 18, EPA 21, respectively. | 56 FR 42623; 8/28/91<br>Fiche# OTS0533017     |
| Diisodecyl phthalate | 68515-49-1 | HECTOXTRFM<br>Morphological transformation | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | mice, BALB 3T3 cells | <i>in vitro</i>   | 200-6320 nl/ml  | Not applicable | The test material, Diisodecyl phthalate (DIDP), was nontoxic, and did not induce significant increased frequency of transformed foci, with or without activation.   | 50 FR 46699;<br>11/12/85<br>Fiche# OTS0509537 |
| Diisodecyl phthalate | 68515-49-1 | HEGTOXMUTA<br>Mutagenicity study           | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | mouse, L5178Y cells  | <i>in vitro</i>   | 2000 - 10,000 nl/ml<br>(nonactivation); 250 - 2000 nl/ml (activation) | Not applicable | The test substance did not induce any significant increases in the mutant frequency at the thymidine kinase (TK) locus, with or without activation.   | 51 FR 39799;<br>10/31/86<br>Fiche# OTS0510528 |

## Results of Testing

| Chemical Name        | CAS No.    | Study Code/Type                       | Protocol/Guideline   | Species                                      | Exposure            | Dose/Concentration   | No. per Group  | Results   | Reference                                  |
|----------------------|------------|---------------------------------------|--|--|---------------------|--|----------------|---|--|
| Diisodecyl phthalate | 68515-49-1 | HESTOX<br>Subchronic oral study       | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | rats   | diet, 21 days       | 0, 0.3, 1.2, 2.5%  | 5/sex/group    | Decreased body weights were evident at 1.2 and 2.5% in males, and to a lesser degree in females. Food intakes were reduced initially in both sexes at 1.2 and 2.5%, the effect persisting throughout treatment in males at 2.5%. Absolute and relative liver and kidney weights were increased in 1.2 and 2.5% (both sexes). At 2.5%, relative testis weights were significantly greater and no lesions were seen histologically. There was a reduction in hepatocyte cytoplasmic basophilia at 1.2 and 2.5%. Lower periportal lipid levels were seen, but not dose related. Serum triglycerides and cholesterol levels were reduced in males at 1.2 and 2.5% level (not dose related). Treatment at 2.5% produced a marked but variable increase in peroxisomes with the females showing greater response. Cyanide-insensitive palmitoyl-CoA was significantly increased at 1.2 and 2.5%. There was a significant increase in the 11- and 12- hydroxylation of lauric acid in all treated males, but in the females the only significant increase was in the 12-hydroxylase level in the 2.5% group. | 51 FR 16203; 5/1/86<br>Fiche# OTS0509543   |
| Dihexyl phthalate    | 68515-50-4 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Fathead minnow                               | flow-through, 96 hr | 0.026-34 mg/L (measured)   | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 48 FR 53159; 11/25/83<br>Fiche# OTS0508481 |
| Dihexyl phthalate    | 68515-50-4 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Fathead minnow                               | static, 96 hr       | <0.0037 to 210 mg/L (5 concentrations/test material up to limit of solubility) | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 48 FR 53159; 11/25/83<br>Fiche# OTS0508481 |
| Dihexyl phthalate    | 68515-50-4 | EEATOX<br>Daphnid acute toxicity      | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Daphnia magna</i>                         | static, 48 hr       | 5 concentrations up to water solubility limits                                 | Not specified  | The 48-hour LC <sub>50</sub> value is >0.35 mg/L.   | 49 FR 44142; 11/2/84<br>Fiche# OTS0508492  |
| Dihexyl phthalate    | 68515-50-4 | EEATOX<br>Acute mysid shrimp toxicity | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Mysid shrimp                                 | static, 96 hr       | 0.056-86.0 mg/L (measured)   | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 49 FR 30114; 7/26/84<br>Fiche# OTS0508488  |
| Dihexyl phthalate    | 68515-50-4 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Rainbow trout                                | flow-through, 96 hr | 0.013-100 mg/L (measured)  | Not specified  | Toxic at concentrations below the limit of aqueous solubility. The 96 hr LC <sub>50</sub> value is 0.82 mg/L.   | 49 FR 18779; 5/2/84<br>Fiche# OTS0508486   |
| Dihexyl phthalate    | 68515-50-4 | EEATOX<br>Acute chironomid toxicity   | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Paratanytarsus parthenogenica</i> (midge) | static, 48 hr       | 0.056-86.3 mg/L (measured)   | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 49 FR 30114; 7/26/84<br>Fiche# OTS0508488  |
| Dihexyl phthalate    | 68515-50-4 | EEATOX<br>Algae acute toxicity        | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Green alga                                   | static, 6 days      | 0.05-1409.4 ppm  | Not applicable | No acute toxicity below the limit of aqueous solubility.  | 50 FR 5421; 2/6/85<br>Fiche# OTS0508496    |
| Dihexyl phthalate    | 68515-50-4 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Bluegill                                     | static, 96 hr       | 0.34-1.0 mg/L (measured)   | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 48 FR 53159; 11/25/83<br>Fiche# OTS0508481 |



## Results of Testing

| Chemical Name  | CAS No.    | Study Code/Type                       | Protocol/Guideline   | Species   | Exposure  | Dose/Concentration                                   | No. per Group  | Results   | Reference                                  |
|--|------------|---------------------------------------|--|---|---|--|----------------|---|--|
| Dihexyl phthalate  | 68515-50-4 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Sheepshead minnow                               | flow-through, 96 hr   | 0.08-60 ppm (measured)                               | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 49 FR 44142; 11/2/84<br>Fiche# OTS0508492  |
| Dihexyl phthalate  | 68515-50-4 | EECLIF<br>Fish early life stage       | 797.1600 (modified)  | Rainbow trout<br>( <i>Oncorhynchus mykiss</i> ) | flow-through, 143 days  | 0, 0.014, 0.028, 0.055, 0.11, 0.22 mg/L (nominal)    | 20             | The results indicate that embryo hatchability, fry survival, standard length and blotted wet weight was not significantly affected at any concentration. No statistical evidence of treatment-related effects were observed during this study at 0.22 mg/L.   | Fiche# OTS0533139                          |
| Dihexyl phthalate  | 68515-50-4 | EECTOX<br>Chronic daphnid toxicity    | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Daphnia magna</i>                            | flow-through, 21 days   | 0.015-80 mg/L (measured)                             | Not specified  | Non-toxic.  | 50 FR 5421; 2/6/85<br>Fiche# OTS0508496    |
| Dihexyl phthalate  | 68515-50-4 | EFBDEG<br>Biodegradation study        | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable                                  | shake flask, 28 days, CO by GC                                      | 4 mg carbon/equivalent                               | Not applicable | Primary biodegradation of 90% or higher and ultimate biodegradation of 55%.   | 48 FR 53159; 11/25/83<br>OTS0508481        |
| Dihexyl phthalate  | 68515-50-4 | EFBDEG<br>Biodegradation study        | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable                                  | 23° C, 24 hr, CO <sub>2</sub> by GC                                 | 1 mg/L   | Not applicable | Primary degradation in excess of 90% in 24 hours.   | 49 FR 44142; 11/2/84<br>Fiche# OTS0508490  |
| Dihexyl phthalate  | 68515-50-4 | EFCHEWSOL<br>Water solubility         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable                                  | deionized water; equilibrate for 24 hr at 25 ± 2° C; analysis by GC | Not specified  | Not applicable | Solubility in distilled water = 0.24 ± 0.05 mg/L.   | 48 FR 34119; 7/27/83<br>Fiche# OTS0508479  |
| Dihexyl phthalate  | 68515-50-4 | EFPCHVPRE<br>Vapor Pressure           | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable                                  | 25 °C, analysis by GC   | Not specified  | Not applicable | Vapor pressure = 1.9 x 10 <sup>-3</sup> .   | 49 FR 44124; 11/2/84<br>Fiche# OTS0508490  |
| Dihexyl phthalate  | 68515-50-4 | EFTSPT<br>Sediment adsorption isother | 796.2750 (modified)  | Not applicable                                  | Not specified   | 0.009, 0.037, 0.074, 0.111, 0.148, 0.222 ml aliquots | Not applicable | The mean percents adsorbed to sediments EPA 8, EPA 18, EPA 21 was 42.0%, 54.0%, and 59.2%, respectively. Correlation coefficients were 0.91533, 0.9187, and 0.9841 for sediments EPA 8, EPA 18, and EPA 21, respectively. HPLC analysis of aqueous adsorption phases and sediment extracts demonstrated stability. The mean C14-mass balance accountability was 112%, 106%, and 103% for sediments EPA 8, EPA 18, EPA 21, respectively. | 56 FR 42623; 8/28/91<br>Fiche# OTS0533017  |
| Di( <i>n</i> -hexyl, <i>n</i> -octyl, <i>n</i> -decyl) phthalate | 68515-51-5 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Bluegill  | static, 96 hr   | 0.34-1.0 mg/L (measured)                             | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 48 FR 53159; 11/25/83<br>Fiche# OTS0508481 |
| Di( <i>n</i> -hexyl, <i>n</i> -octyl, <i>n</i> -decyl) phthalate | 68515-51-5 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Rainbow trout                                   | flow-through, 96 hr   | 0.013-100 mg/L (measured)                            | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 49 FR 18779; 5/2/84<br>Fiche# OTS0508486   |
| Di( <i>n</i> -hexyl, <i>n</i> -octyl, <i>n</i> -decyl) phthalate | 68515-51-5 | EEATOX<br>Acute chironomid toxicity   | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Paratanytarsus parthenogenica</i> (midge)    | static, 48 hr   | 0.056-86.3 mg/L (measured)                           | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 49 FR 30114; 7/26/84<br>Fiche# OTS0508488  |

## Results of Testing

| Chemical Name  | CAS No.    | Study Code/Type                                  | Protocol/Guideline   | Species              | Exposure   | Dose/Concentration   | No. per Group  | Results   | Reference                                     |
|--|------------|--|--|----------------------|--|--|----------------|---|---|
| Di( <i>n</i> -hexyl, <i>n</i> -octyl, <i>n</i> -decyl) phthalate | 68515-51-5 | EEATOX<br>Acute fish toxicity                    | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Sheepshead minnow    | flow-through, 96 hr  | 0.08-60 ppm (measured)   | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 49 FR 44142; 11/2/84<br>Fiche# OTS0508492     |
| Di( <i>n</i> -hexyl, <i>n</i> -octyl, <i>n</i> -decyl) phthalate | 68515-51-5 | EEATOX<br>Acute fish toxicity                    | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Fathead minnow       | flow-through, 96 hr  | 0.026-34 mg/L (measured)   | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0508481 |
| Di( <i>n</i> -hexyl, <i>n</i> -octyl, <i>n</i> -decyl) phthalate | 68515-51-5 | EEATOX<br>Algae acute toxicity                   | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Green alga           | static, 6 days   | 0.05-1409.4 ppm  | Not applicable | No acute toxicity below the limit of aqueous solubility.  | 50 FR 5421; 2/6/85<br>Fiche# OTS0508496       |
| Di( <i>n</i> -hexyl, <i>n</i> -octyl, <i>n</i> -decyl) phthalate | 68515-51-5 | EEATOX<br>Acute fish toxicity                    | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Fathead minnow       | static, 96 hr  | <0.0037 to 210 mg/L (5 concentrations/test material up to limit of solubility) | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0508481 |
| Di( <i>n</i> -hexyl, <i>n</i> -octyl, <i>n</i> -decyl) phthalate | 68515-51-5 | EEATOX<br>Daphnid acute toxicity                 | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Daphnia magna</i> | static, 48 hr  | 5 concentrations up to water solubility limits                                 | Not specified  | The 48-hour LC <sub>50</sub> value is >0.42 mg/L.   | 49 FR 44142; 11/2/84<br>Fiche# OTS0508492     |
| Di( <i>n</i> -hexyl, <i>n</i> -octyl, <i>n</i> -decyl) phthalate | 68515-51-5 | EEATOX<br>Acute mysid shrimp toxicity            | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Mysid shrimp         | static, 96 hr  | 0.056-86.0 mg/L (measured)   | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 49 FR 30114; 7/26/84<br>Fiche# OTS0508488     |
| Di( <i>n</i> -hexyl, <i>n</i> -octyl, <i>n</i> -decyl) phthalate | 68515-51-5 | EECTOX<br>Chronic daphnid toxicity               | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Daphnia magna</i> | flow-through, 21 days  | 0.015-80 mg/L (measured)   | Not specified  | Non-toxic.  | 50 FR 5421; 2/6/85<br>Fiche# OTS0508496       |
| Di( <i>n</i> -hexyl, <i>n</i> -octyl, <i>n</i> -decyl) phthalate | 68515-51-5 | EFBDEG<br>Biodegradation study                   | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable       | shake flask, 28 d, CO by GC  | 4 mg carbon/equivalent   | Not applicable | Primary biodegradation of 90% or higher and ultimate biodegradation of 55%.   | 48 FR 53159;<br>11/25/83<br>OTS0508481        |
| Di( <i>n</i> -hexyl, <i>n</i> -octyl, <i>n</i> -decyl) phthalate | 68515-51-5 | EFBDEG<br>Biodegradation study                   | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable       | 23° C, 24 hr, CO <sub>2</sub> by GC                                | 1 mg/L   | Not applicable | Exhibited at least 50% primary degradation in 24 hours.   | 49 FR 44142; 11/2/84<br>Fiche# OTS0508490     |
| Di( <i>n</i> -hexyl, <i>n</i> -octyl, <i>n</i> -decyl) phthalate | 68515-51-5 | EFCHWSOL<br>Water solubility                     | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable       | deionized water; equilibrate for 24 h at 25 ± 2° C; analysis by GC | Not specified  | Not applicable | Solubility in distilled water = 0.9 ± 0.5 mg/L.   | 48 FR 34119; 7/27/83<br>Fiche# OTS0508479     |
| Di( <i>n</i> -hexyl, <i>n</i> -octyl, <i>n</i> -decyl) phthalate | 68515-51-5 | EFPCHEVPRE<br>Vapor Pressure                     | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable       | 25 °C, analysis by GC  | Not specified  | Not applicable | Vapor pressure = 6.5 x 10 <sup>-4</sup> .   | 49 FR 44124; 11/2/84<br>Fiche# OTS0508490     |
| Di( <i>n</i> -hexyl, <i>n</i> -octyl, <i>n</i> -decyl) phthalate | 68515-51-5 | HECTOXTRFM<br>Morphological transformation study | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | mice, BALB 3T3 cells | <i>in vitro</i>  | 63-6320 nl/ml  | Not applicable | The test material, di( <i>n</i> -hexyl, <i>n</i> -octyl, <i>n</i> -decyl) phthalate (610P), did not induce an increased number of transformed foci at any of the concentrations tested, with or without activation. | 50 FR 46699;<br>11/12/85<br>Fiche# OTS0509537 |

## Results of Testing

| Chemical Name  | CAS No.    | Study Code/Type                       | Protocol/Guideline   | Species                                      | Exposure            | Dose/Concentration   | No. per Group  | Results   | Reference                                     |
|--|------------|---------------------------------------|--|--|---------------------|--|----------------|---|---|
| Di( <i>n</i> -hexyl, <i>n</i> -octyl, <i>n</i> -decyl) phthalate | 68515-51-5 | HEGTOXMUTA<br>Mutagenicity study      | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | mouse, L5178Y<br>cells                       | <i>in vitro</i>     | 9.77, 19.5, 39.1, 78.1, 156, 313, 625, 1250, 2500, 5000 nl/ml                  | Not applicable | In the presence of metabolic activation, the test material, at 5000 nl/ml was lethal and at 1250 and 2500 nl/ml, it was highly toxic. In the absence of metabolic activation, the test material at 1250, 2500, and 5000 nl/ml was toxic. Treatments from 9.77 to 625 nl/ml induced low to moderate toxicities in both the presence and absence of metabolic activation.   | 51 FR 6468; 2/24/86<br>Fiche# OTS0509537      |
| Di( <i>n</i> -hexyl, <i>n</i> -octyl, <i>n</i> -decyl) phthalate | 68515-51-5 | HESTOX<br>Subchronic oral study       | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | rats   | diet, 21 days       | 0, 0.6, 1.2, 2.5%  | 5/sex/group    | Treatment did not significantly influence the bodyweights or food intakes of the treated animals. In both sexes the weights and relative weights of the livers were increased in all treated groups. In the females there was a reduction in the hepatocyte cytoplasmic basophilia in the groups fed 2.5% and in one rat fed 1.2%. In the male the reduction was obscured by extensive lipid deposition in the treated groups. In the histological examination this lipid was seen as vacuolation and was accompanied by slight increases in mitotic activity and cell necrosis. In the females slight necrosis and increased mitotic activity was confined to a few animals from the 1.2 and 2.5% groups. Serum cholesterol levels were significantly reduced in the female treated groups, and the male 0.6% group (not dose related). Male rats at 2.5% had a slight increase in peroxisome numbers and females a moderate increase. There was increases of palmitoyl CoA oxidation in both sexes fed 1.2 and 2.5%. Lauric acid 12- hydroxylase activity was increased significantly in both sexes fed 2.5%. The 11-hydroxylase activity was significantly increased in all treated females. | 51 FR 16203; 5/1/86<br>Fiche# OTS0509543      |
| Diethyl phthalate  | 84-66-2    | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Fathead<br>minnow                            | flow-through, 96 hr | 0.026-34 mg/L<br>(measured)  | Not specified  | Toxic to the fathead minnow. The 96-hour LC <sub>50</sub> value is 17 mg/L.   | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0508481 |
| Diethyl phthalate  | 84-66-2    | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Fathead<br>minnow                            | static, 96 hr       | <0.0037 to 210 mg/L (5 concentrations/test material up to limit of solubility) | Not specified  | Toxic at concentrations below the limit of aqueous solubility. The LC <sub>50</sub> value is 17 mg/L.   | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0508481 |
| Diethyl phthalate  | 84-66-2    | EEATOX<br>Daphnid acute toxicity      | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Daphnia magna</i>                         | static, 48 hr       | 5 concentrations up to water solubility limits                                 | Not specified  | The 48-hour LC <sub>50</sub> value is 90 mg/L.  | 49 FR 44142; 11/2/84<br>Fiche# OTS0508492     |
| Diethyl phthalate  | 84-66-2    | EEATOX<br>Algae acute toxicity        | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Green alga                                   | static, 6 days      | 0.05-1409.4 ppm  | Not applicable | Toxic to the test algae. The EC <sub>50</sub> (population growth) value is 30.3 mg/L.   | 50 FR 5421; 2/6/85<br>Fiche# OTS0508496       |
| Diethyl phthalate  | 84-66-2    | EEATOX<br>Acute mysid shrimp toxicity | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Mysid shrimp                                 | static, 96 hr       | 0.056-86.0 mg/L<br>(measured)  | Not specified  | Toxic to the mysid shrimp. The 96-hour LC <sub>50</sub> value is 18.3 mg/L  | 49 FR 30114; 7/26/84<br>Fiche# OTS0508488     |
| Diethyl phthalate  | 84-66-2    | EEATOX<br>Acute chironomid toxicity   | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Paratanytarsus parthenogenica</i> (midge) | static, 48 hr       | 0.056-86.3 mg/L<br>(measured)  | Not specified  | Toxic to the midge. The 48-hour LC <sub>50</sub> value is 18.3 mg/L.  | 49 FR 30114; 7/26/84<br>Fiche# OTS0508488     |

## Results of Testing

| Chemical Name     | CAS No. | Study Code/Type                       | Protocol/Guideline   | Species              | Exposure   | Dose/Concentration   | No. per Group  | Results   | Reference                                     |
|-------------------|---------|---------------------------------------|--|----------------------|--|--|----------------|---|---|
| Diethyl phthalate | 84-66-2 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Sheepshead minnow    | flow-through, 96 hr  | 0.08-60 ppm (measured)   | Not specified  | Toxic to the sheepshead minnow. The 96-hour LC <sub>50</sub> value is 29 mg/L                               | 49 FR 44142; 11/2/84<br>Fiche# OTS0508492     |
| Diethyl phthalate | 84-66-2 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Bluegill             | static, 96 hr  | 0.34-1.0 mg/L (measured)   | Not specified  | Toxic to the bluegill. The 96-hour LC <sub>50</sub> value is 22 mg/L.                                       | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0508481 |
| Diethyl phthalate | 84-66-2 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Rainbow trout        | flow-through, 96 hr  | 0.013-100 mg/L (measured)  | Not specified  | Toxic at concentrations below the limit of aqueous solubility. The 96 hr LC <sub>50</sub> value is 12 mg/L. | 49 FR 18779; 5/2/84<br>Fiche# OTS0508486      |
| Diethyl phthalate | 84-66-2 | EECTOX<br>Chronic daphnid toxicity    | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Daphnia magna</i> | flow-through, 21 days  | 0.015-80 mg/L (measured)   | Not specified  | Toxic to <i>Daphnia magna</i> . Maximum affect test concentration (MATC) was 38 mg/L.                       | 50 FR 5421; 2/6/85<br>Fiche# OTS0508496       |
| Diethyl phthalate | 84-66-2 | EFBDEG<br>Biodegradation study        | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable       | 23° C, 24 hr, CO <sub>2</sub> by GC                                | 1 mg/L   | Not applicable | Primary degradation in excess of 90% in 24 hours.   | 49 FR 44142; 11/2/84<br>Fiche# OTS0508490     |
| Diethyl phthalate | 84-66-2 | EFBDEG<br>Biodegradation study        | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable       | shake flask, 28 d, CO by GC  | 4 mg carbon/equivalent   | Not applicable | Primary biodegradation of 90% or higher and ultimate biodegradation of 55%.                                 | 48 FR 53159;<br>11/25/83<br>OTS0508481        |
| Diethyl phthalate | 84-66-2 | EFCHEWSOL<br>Water solubility         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable       | deionized water; equilibrate for 24 h at 25 ± 2° C; analysis by GC | Not specified  | Not applicable | Solubility in distilled water = 4000 ± 60 mg/L.   | 48 FR 34119; 7/27/83<br>Fiche# OTS0508479     |
| Diethyl phthalate | 84-66-2 | EFPCHEPART<br>Octanol/water partition | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable       | octanol/deionized water at 25 °C, analysis by GC                   | 10 <sup>-2</sup> M   | Not applicable | The log Kow value with standard errors was 2.24 ± 0.004.  | 49 FR 44142; 11/2/84<br>Fiche# OTS0508491     |
| Diethyl phthalate | 84-66-2 | EFPCHEVPRE<br>Vapor Pressure          | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable       | 25 °C, analysis by GC  | Not specified  | Not applicable | Vapor pressure = 2.2 x 10 <sup>-1</sup> .   | 49 FR 44124; 11/2/84<br>Fiche# OTS0508490     |
| Dibutyl phthalate | 84-74-2 | EEATOX<br>Acute mysid shrimp toxicity | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Mysid shrimp         | static, 96 hr  | 0.056-86.0 mg/L (measured)   | Not specified  | Toxic to the mysid shrimp. The 96-hour LC <sub>50</sub> value is 0.75 mg/L                                  | 49 FR 30114; 7/26/84<br>Fiche# OTS0508488     |
| Dibutyl phthalate | 84-74-2 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Fathead minnow       | static, 96 hr  | <0.0037 to 210 mg/L (5 concentrations/test material up to limit of solubility) | Not specified  | Toxic at concentrations below the limit of aqueous solubility. The LC <sub>50</sub> value is 3.0 mg/L.      | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0508481 |
| Dibutyl phthalate | 84-74-2 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Sheepshead minnow    | flow-through, 96 hr  | 0.08-60 ppm (measured)   | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 49 FR 44142; 11/2/84<br>Fiche# OTS0508492     |
| Dibutyl phthalate | 84-74-2 | EEATOX<br>Algae acute toxicity        | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Green alga           | static, 6 days   | 0.05-1409.4 ppm  | Not applicable | Toxic to the test algae. The EC <sub>50</sub> (population growth) value is 0.75 mg/L.                       | 50 FR 5421; 2/6/85<br>Fiche# OTS0508496       |

## Results of Testing

| Chemical Name     | CAS No. | Study Code/Type                       | Protocol/Guideline   | Species   | Exposure   | Dose/Concentration                             | No. per Group  | Results  | Reference                                     |
|-------------------|---------|---------------------------------------|--|---|--|--|----------------|--|---|
| Dibutyl phthalate | 84-74-2 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Bluegill  | static, 96 hr  | 0.34-1.0 mg/L<br>(measured)                    | Not specified  | Toxic to the bluegill. The 96-hour LC <sub>50</sub> value is 0.85 mg/L.  | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0508481 |
| Dibutyl phthalate | 84-74-2 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Fathead minnow                                  | flow-through, 96 hr  | 0.026-34 mg/L<br>(measured)                    | Not specified  | Toxic to the fathead minnow. The 96-hour LC <sub>50</sub> value is 0.92 mg/L.  | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0508481 |
| Dibutyl phthalate | 84-74-2 | EEATOX<br>Acute fish toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Rainbow trout                                   | flow-through, 96 hr  | 0.013-100 mg/L<br>(measured)                   | Not specified  | Toxic at concentrations below the limit of aqueous solubility. The 96 hr LC <sub>50</sub> value is 1.6 mg/L.   | 49 FR 18779; 5/2/84<br>Fiche# OTS0508486      |
| Dibutyl phthalate | 84-74-2 | EEATOX<br>Acute chironomid toxicity   | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Paratanytarsus parthenogenica</i> (midge)    | static, 48 hr  | 0.056-86.3 mg/L<br>(measured)                  | Not specified  | Toxic to the midge. The 48-hour LC <sub>50</sub> value is 0.75 mg/L.   | 49 FR 30114; 7/26/84<br>Fiche# OTS0508488     |
| Dibutyl phthalate | 84-74-2 | EEATOX<br>Daphnid acute toxicity      | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Daphnia magna</i>                            | static, 48 hr  | 5 concentrations up to water solubility limits | Not specified  | The 48-hour LC <sub>50</sub> value is 3.4 mg/L.  | 49 FR 44142; 11/2/84<br>Fiche# OTS0508492     |
| Dibutyl phthalate | 84-74-2 | EECLIF<br>Fish early life stage       | 797.1600 (modified)  | Rainbow trout<br>( <i>Oncorhynchus mykiss</i> ) | flow-through, 99 days  | 0, 0.14, 0.26, 0.52, 1.0, 2.0 mg/L (nominal)   | 30             | Exposure of embryos, larvae, and juvenile fish to the test substance resulted in a lowest observed effect concentration of 0.26 mg/L, a no observed effect concentration (NOEC) of 0.14 mg/L, and a maximum acceptable toxicant concentration (MATC) of 0.14 mg/L. No rainbow trout survived at the three highest tested concentrations. The length and weight of rainbow trout after 99 days of exposure were significantly reduced at 0.26 mg/L. | Fiche# OTS0533141                             |
| Dibutyl phthalate | 84-74-2 | EECTOX<br>Chronic daphnid toxicity    | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Daphnia magna</i>                            | flow-through, 21 days  | 0.015-80 mg/L<br>(measured)                    | Not specified  | Toxic to <i>Daphnia magna</i> . Maximum affect test concentration (MATC) was 1.5 mg/L.   | 50 FR 5421; 2/6/85<br>Fiche# OTS0508496       |
| Dibutyl phthalate | 84-74-2 | EFBDEG<br>Biodegradation study        | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable                                  | 23° C, 24 hr, CO <sub>2</sub> by GC                                | 1 mg/L   | Not applicable | Primary degradation in excess of 90% in 24 hours.  | 49 FR 44142; 11/2/84<br>Fiche# OTS0508490     |
| Dibutyl phthalate | 84-74-2 | EFBDEG<br>Biodegradation study        | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable                                  | shake flask, 28 d, CO by GC  | 4 mg carbon/equivalent                         | Not applicable | Primary biodegradation of 90% or higher and ultimate biodegradation of 55%.  | 48 FR 53159;<br>11/25/83<br>OTS0508481        |
| Dibutyl phthalate | 84-74-2 | EFCHEWSOL<br>Water solubility         | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable                                  | deionized water; equilibrate for 24 h at 25 ± 2° C; analysis by GC | Not specified                                  | Not applicable | Solubility in distilled water = 11.2 ± 0.3 mg/L.   | 48 FR 34119; 7/27/83<br>Fiche# OTS0508479     |
| Dibutyl phthalate | 84-74-2 | EFPCHEPART<br>Octanol/water partition | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable                                  | octanol/deionized water at 25 °C, analysis by GC                   | 10 <sup>-2</sup> M                             | Not applicable | The log Kow value with standard errors was 4.79 ± 0.094.   | 49 FR 44142; 11/2/84<br>Fiche# OTS0508491     |
| Dibutyl phthalate | 84-74-2 | EFPCHEVPRE<br>Vapor Pressure          | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Not applicable                                  | 25 °C, analysis by GC  | Not specified                                  | Not applicable | Vapor pressure = 9.7 x 10 <sup>-3</sup> .  | 49 FR 44124; 11/2/84<br>Fiche# OTS0508490     |

## Results of Testing

| Chemical Name                  | CAS No. | Study Code/Type                                | Protocol/Guideline   | Species                                      | Exposure            | Dose/Concentration   | No. per Group  | Results  | Reference                                  |
|--------------------------------|---------|--|--|--|---------------------|--|----------------|--|--|
| Di- <i>n</i> -butyl phthalate  | 84-74-2 | HECTOXTRFM<br>Morphological transformation     | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | mice, BALB 3T3 cells                         | <i>in vitro</i>     | 3.4-82.3 nl/ml   | Not applicable | The test material, di- <i>n</i> -butyl phthalate (DBP), did not induce an increased number of transformed foci at any of the concentrations tested, with or without activation.  | 50 FR 46699; 11/12/85<br>Fiche# OTS0509537 |
| Di( <i>n</i> -butyl) phthalate | 84-74-2 | HEGTOXMUTA<br>Mutagenicity study               | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | mouse, L5178Y cells                          | <i>in vitro</i>     | 9.77, 19.5, 39.1, 78.1, 156, 313, 625, 1250, 2500, 5000 nl/ml                  | Not applicable | The test material, DBP, under nonactivated conditions, was highly toxic at 78.1 nl/ml after 48 hours. The dose-level of 156 nl/ml was lethal to the test cells. In the presence of metabolic activation, the test material formed a precipitate at 5000 nl/ml after 24 hours. At 1250 nl/ml, the test material was lethal and the 625 and 313 nl/ml media were highly toxic. | 51 FR 6468; 2/24/86<br>Fiche# OTS0509537   |
| Butyl benzyl phthalate         | 85-68-7 | EEATOX<br>Acute invertebrate toxicity          | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42070) | Mayfly                                       | flow-through, 96 hr | 0.082, 0.18, 0.32, 0.77, 1.6 mg/L (measured)                                   | Not specified  | The 96-hour LC <sub>50</sub> value was 1.1 mg/L. Loss of equilibrium at 1.6 mg/L was the only behavioral/sublethal response. The no-observed-effect concentration was <0.082 mg/L (some mortality was observed at this concentration level).   | 52 FR 2151; 1/20/87<br>Fiche# OTS0522401   |
| Butyl benzyl phthalate         | 85-68-7 | EEATOX<br>Daphnid acute toxicity               | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42070) | <i>Daphnia magna</i>                         | static, 48 hr       | 5 concentrations up to water solubility limits                                 | Not specified  | The 48-hour LC <sub>50</sub> value is >1.4 mg/L.   | 49 FR 44142; 11/2/84<br>Fiche# OTS0508492  |
| Butyl benzyl phthalate         | 85-68-7 | EEATOX<br>Acute mysid shrimp toxicity          | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42070) | Mysid shrimp                                 | static, 96 hr       | 0.056-86.0 mg/L (measured)   | Not specified  | No acute toxicity below the limit of aqueous solubility.   | 49 FR 30114; 7/26/84<br>Fiche# OTS0508488  |
| Butyl benzyl phthalate         | 85-68-7 | EEATOX<br>Acute fish toxicity                  | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42070) | Sheepshead minnow                            | flow-through, 96 hr | 0.08-60 ppm (measured)   | Not specified  | No acute toxicity below the limit of aqueous solubility.   | 49 FR 44142; 11/2/84<br>Fiche# OTS0508492  |
| Butyl benzyl phthalate         | 85-68-7 | EEATOX<br>Acute aquatic toxicity, invertebrate | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42070) | <i>Nereis/ Neanthes virens</i> (polychaetes) | flow-through, 96 hr | 0.31, 0.53, 0.72, 1.7, 3.0 mg/L (measured)                                     | Not specified  | There were no observations of mortality or adverse effects at any of the concentration levels tested. The LC <sub>50</sub> value was greater than 3.0 mg/L.  | 52 FR 2152; 1/20/87<br>Fiche# OTS0522399   |
| Butyl benzyl phthalate         | 85-68-7 | EEATOX<br>Acute aquatic toxicity, invertebrate | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42070) | <i>Procambarus</i> (crayfish)                | flow-through, 96 hr | 0.12, 0.25, 0.55, 1.1, 2.4 mg/L (measured)                                     | Not specified  | The 96-hour LC <sub>50</sub> value was >2.4 mg/L. The no-observed-effect concentration was 2.4 mg/L.   | 51 FR 39799; 10/31/86<br>Fiche# OTS0522398 |
| Butyl benzyl phthalate         | 85-68-7 | EEATOX<br>Oyster Acute toxicity                | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42070) | Eastern oysters                              | flow-through, 96 hr | 0.19-1.4 mg/L (measured)   | Not specified  | The percentage of reduction for new shell growth ranged from 0% at the 0.38 mg/L exposure level to 53% at the 1.4 mg/L level. The 96-hour EC <sub>50</sub> (and 95% confidence interval) was 1.3 mg/L (1.1 to 1.7 mg/L).   | 52 FR 2152; 1/20/87<br>Fiche# OTS0522399   |
| Butyl benzyl phthalate         | 85-68-7 | EEATOX<br>Acute aquatic toxicity, invertebrate | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42070) | Grass shrimp                                 | flow-through, 96 hr | 0.37, 0.50, 0.78, 1.3, 2.7 mg/L (measured)                                     | Not specified  | Throughout the 96-hour exposure period, no mortalities or adverse effects were observed among the test animals exposed to any concentration. The 96-hour LC <sub>50</sub> was greater than 2.7 mg/L.   | 52 FR 2152; 1/20/87<br>Fiche# OTS0522399   |
| Butyl benzyl phthalate         | 85-68-7 | EEATOX<br>Acute aquatic toxicity, invertebrate | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42070) | Pink shrimp                                  | flow-through, 96 hr | 0.60, 0.62, 0.90, 1.4, 3.4 mg/L (measured)                                     | Not specified  | Throughout the 96-hour exposure period, no mortalities or adverse effects were observed among the test animals exposed to any concentration. The 96-hour LC <sub>50</sub> was greater than 3.4 mg/L.   | 52 FR 2152; 1/20/87<br>Fiche# OTS0522399   |
| Butyl benzyl phthalate         | 85-68-7 | EEATOX<br>Acute fish toxicity                  | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42070) | Fathead minnow                               | static, 96 hr       | <0.0037 to 210 mg/L (5 concentrations/test material up to limit of solubility) | Not specified  | No acute toxicity below the limit of aqueous solubility.   | 48 FR 53159; 11/25/83<br>Fiche# OTS0508481 |

## Results of Testing

| Chemical Name          | CAS No. | Study Code/Type                          | Protocol/Guideline   | Species              | Exposure  | Dose/Concentration   | No. per Group  | Results   | Reference                                     |
|------------------------|---------|--|--|----------------------|---|--|----------------|---|---|
| Butyl benzyl phthalate | 85-68-7 | EEATOX<br>Acute fish toxicity            | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42070) | Rainbow trout        | flow-through, 96 hr   | 0.013-100 mg/L<br>(measured)   | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 49 FR 18779; 5/2/84<br>Fiche# OTS0508486      |
| Butyl benzyl phthalate | 85-68-7 | EEATOX<br>Algae acute toxicity           | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42070) | Green alga           | static, 6 days  | 0.05-1409.4 ppm  | Not applicable | No acute toxicity below the limit of aqueous solubility.  | 50 FR 5421; 2/6/85<br>Fiche# OTS0508496       |
| Butyl benzyl phthalate | 85-68-7 | EEATOX<br>Acute invertebrate toxicity    | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42070) | Hydra                | flow-through, 96 hr   | 0.12, 0.25, 0.50, 1.0, 2.0 mg/L (nominal)  | Not specified  | The 96-hour EC <sub>50</sub> (mortality; presence of "tulip stage") value (and 95% confidence interval values) was 1.1 mg/L (0.5 to 2.0 mg/L). At the concentration level 2.0 mg/L, 35% mortality was observed. The no-observed-effect concentration value was 0.5 mg/L.  | 51 FR 27598; 8/1/86<br>Fiche# OTS0522397      |
| Butyl benzyl phthalate | 85-68-7 | EEATOX<br>Acute fish toxicity            | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42070) | Fathead minnow       | flow-through, 96 hr   | 0.026-34 mg/L<br>(measured)  | Not specified  | Toxic to the fathead minnow. The 96-hour LC <sub>50</sub> value is 1.5 mg/L.  | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0508481 |
| Butyl benzyl phthalate | 85-68-7 | EEBIOC<br>Mollusk bioconcentration       | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42070) | Eastern oyster       | continuous in natural seawater, 11 d, then 42 d depuration period                   | 0.020 mg/L of 14C-BBP (nominal)  | Not specified  | Concentration of residues reached steady-state in 3 days, yielding a whole-body-tissue bioconcentration factor of 135x. The projected half-life was calculated to be 7.4 days. Partial elimination of <sup>14</sup> C-residue from whole body tissues was observed within 6 hours of depuration, and 50% was eliminated between day 1 and 2 of depuration. By day 14, 85% was eliminated. | 52 FR 2152; 1/20/87<br>Fiche# OTS0522399      |
| Butyl benzyl phthalate | 85-68-7 | EECLIF<br>Fish early life stage test     | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42070) | Rainbow trout        | flow-through, 109 days post-hatch   | 0, 0.012, 0.021, 0.044, 0.095, 0.20 mg/L (mean measured levels of <sup>14</sup> C-BBP) | Not specified  | This study was terminated 11 days early (intended to be a 120 day study) due to random unexplained fish mortality. Fry growth (length) was reduced at the high-dose at 35 and 60 days, but returned to normal at 90 and 109 days. No effects were noted on fry growth in weight, hatchability, or survival of fry. The MATC at the end of the study was >0.20 mg/L.                       | 52 FR 2152; 1/20/87<br>Fiche# OTS0522403      |
| Butyl benzyl phthalate | 85-68-7 | EECTOX<br>Mysid shrimp chronic toxicity  | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42070) | Mysid shrimp         | flow-through, 28 days   | 0.024-0.75 mg/L<br>(measured)  | Not specified  | Survival rate of the test animals at the highest test concentration was significantly less than the control. Development of the test animals exposed to 0.75 mg/L was retarded. Reproduction was also reduced at 0.17 and 0.75 mg/L. The estimated maximum acceptable toxicant concentration (MATC) after 28 days was between 0.075 and 0.17 mg/L.  | 52 FR 2151; 1/20/87<br>Fiche# OTS0522399      |
| Butyl benzyl phthalate | 85-68-7 | EECTOX<br>Chronic daphnid toxicity       | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42070) | <i>Daphnia magna</i> | flow-through, 21 days   | 0.015-80 mg/L<br>(measured)  | Not specified  | Toxic to <i>Daphnia magna</i> . Maximum affect test concentration (MATC) was 0.63 mg/L.   | 50 FR 5421; 2/6/85<br>Fiche# OTS0508496       |
| Butyl benzyl phthalate | 85-68-7 | EFBDEG<br>Microcosm biodegradation study | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42070) | Not applicable       | river water and sediment cores, <sup>14</sup> CO <sub>2</sub> , sterile water; 30 d | 10, 100 µg/L   | Not applicable | The test material is readily degraded in water. The estimated half-life for primary degradation was 2 days or less.   | 52 FR 2152; 1/20/87<br>Fiche# OTS0522402      |
| Butyl benzyl phthalate | 85-68-7 | EFPCHEVPRE<br>Vapor Pressure             | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42070) | Not applicable       | 25 °C, analysis by GC   | Not specified  | Not applicable | Vapor pressure = 1.1 x 10 <sup>-3</sup> .   | 49 FR 44124; 11/2/84<br>Fiche# OTS0508490     |

## Results of Testing

| Chemical Name                | CAS No. | Study Code/Type                           | Protocol/Guideline   | Species              | Exposure             | Dose/Concentration  | No. per Group  | Results   | Reference                                     |
|------------------------------|---------|---|--|----------------------|----------------------|---|----------------|---|---|
| Butyl benzyl phthalate       | 85-68-7 | EFPCHEWSOL<br>Water solubility study      | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42070) | Not applicable       | well water           | Not applicable  | Not applicable | water solubility = 2.6 mg/L   | 51 FR 27598; 8/1/86<br>Fiche# OTS0522397      |
| Butyl benzyl phthalate       | 85-68-7 | HECTOXCARC                                | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42070) | rats                 | oral (diet), 2 years | 0, 3,000, 6,000, 12,000 ppm (males); 0, 6,000, 12,000, 24,000 ppm (females) | 60/sex/group   | There was some evidence of carcinogenic activity in male rats based on the increased incidences of pancreatic acinar cell adenoma and of acinar cell adenoma or carcinoma (combined). There was equivocal evidence of carcinogenic activity in females based on the marginally increased incidences of pancreatic acinar cell adenoma and of transitional epithelial papilloma of the urinary bladder.  | T-458   |
| Butyl benzyl phthalate       | 85-68-7 | HECTOXRFM<br>Morphological transformation | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42070) | mice, BALB 3T3 cells | <i>in vitro</i>      | 10-160 nl/ml  | Not applicable | The test material, butyl benzyl phthalate (BBP), did not induce an increased number of transformed foci at any of the concentrations tested, with or without activation.  | 50 FR 46699;<br>11/12/85<br>Fiche# OTS0509537 |
| Butyl benzyl phthalate       | 85-68-7 | HEGTOXMUTA<br>Mutagenicity study          | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42070) | mouse, L5178Y cells  | <i>in vitro</i>      | 9.77, 19.5, 39.1, 78.1, 156, 313, 625, 1250, 2500, 5000 nl/ml               | Not applicable | In the absence of metabolic activation, the test material, BBP, was highly toxic to cells at 625 and 1250 nl/ml and treatment with 2500 nl/ml was lethal. In the presence of metabolic activation, the test material was lethal at 2500 and 5000 nl/ml and toxic at 1250 nl/ml.   | 51 FR 6468; 2/24/86<br>Fiche# OTS0509537      |
| Butyl benzyl phthalate       | 85-68-7 | HESTOX<br>Subchronic oral study           | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42070) | rats                 | diet, 21 days        | 0, 1.2, 2.5%  | 5/sex/group    | Toxicity was evident by statistical differences between dosed groups and controls for: mean body weights (2.5 and 1.2% males, and 2.5% females), food consumption values (2.5% both sexes), relative liver and kidney weights (all treated groups) and relative testis weights (2.5%). There was a decrease in serum triglycerides for the 1.2 and 2.5% males and an increase in triglycerides for the 2.5% females. There was a moderate increase in the amount of peroxisome proliferation for the high-dose animals. Liver biochemistry revealed statistically significant differences between treated and controls as indicated by cyanide-insensitive palmitoyl-CoA oxidation levels (all treated males and 2.5% females), lauric acid 11- and 12- hydroxylase activities (all treated males and 2.5% females) and hepatic microsomal protein levels (2.5% males). Treatment related histological changes included reduction in cytoplasmic basophilia in the livers (2.5% both sexes) and severe testicular atrophy (2.5%). | 51 FR 16203; 5/1/86<br>Fiche# OTS0509543      |
| Butyl 2-ethylhexyl phthalate | 85-69-8 | EEATOX<br>Algae acute toxicity            | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Green alga           | static, 6 days       | 0.05-1409.4 ppm   | Not applicable | No acute toxicity below the limit of aqueous solubility.  | 50 FR 5421; 2/6/85<br>Fiche# OTS0508496       |
| Butyl 2-ethylhexyl phthalate | 85-69-8 | EEATOX<br>Acute fish toxicity             | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | Sheepshead minnow    | flow-through, 96 hr  | 0.08-60 ppm (measured)  | Not specified  | No acute toxicity below the limit of aqueous solubility.  | 49 FR 44142; 11/2/84<br>Fiche# OTS0508492     |
| Butyl 2-ethylhexyl phthalate | 85-69-8 | EEATOX<br>Daphnid acute toxicity          | Non-TSCA<br>Protocol/Guideline<br>(see docket# OPTS-42005) | <i>Daphnia magna</i> | static, 48 hr        | 5 concentrations up to water solubility limits                              | Not specified  | The 48-hour LC <sub>50</sub> value is >0.10 mg/L.   | 49 FR 44142; 11/2/84<br>Fiche# OTS0508492     |



## Results of Testing

| Chemical Name                | CAS No.  | Study Code/Type                                   | Protocol/Guideline                                   | Species                                       | Exposure  | Dose/Concentration   | No. per Group           | Results   | Reference                                     |
|------------------------------|----------|---|--|---|---|--|-------------------------|---|---|
| Butyl 2-ethylhexyl phthalate | 85-69-8  | EEATOX<br>Acute chironomid toxicity               | Non-TSCA Protocol/Guideline (see docket# OPTS-42005) | <i>Paratanytarsus parthenogenica</i> (midge)  | static, 48 hr   | 0.056-86.3 mg/L (measured)   | Not specified           | No acute toxicity below the limit of aqueous solubility.  | 49 FR 30114; 7/26/84<br>Fiche# OTS0508488     |
| Butyl 2-ethylhexyl phthalate | 85-69-8  | EEATOX<br>Acute fish toxicity                     | Non-TSCA Protocol/Guideline (see docket# OPTS-42005) | Rainbow trout                                 | flow-through, 96 hr   | 0.013-100 mg/L (measured)  | Not specified           | No acute toxicity below the limit of aqueous solubility.  | 49 FR 18779; 5/2/84<br>Fiche# OTS0508486      |
| Butyl 2-ethylhexyl phthalate | 85-69-8  | EEATOX<br>Acute fish toxicity                     | Non-TSCA Protocol/Guideline (see docket# OPTS-42005) | Bluegill                                      | static, 96 hr   | 0.34-1.0 mg/L (measured)   | Not specified           | No acute toxicity below the limit of aqueous solubility.  | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0508481 |
| Butyl 2-ethylhexyl phthalate | 85-69-8  | EEATOX<br>Acute mysid shrimp toxicity             | Non-TSCA Protocol/Guideline (see docket# OPTS-42005) | Mysid shrimp                                  | static, 96 hr   | 0.056-86.0 mg/L (measured)   | Not specified           | No acute toxicity below the limit of aqueous solubility.  | 49 FR 30114; 7/26/84<br>Fiche# OTS0508488     |
| Butyl 2-ethylhexyl phthalate | 85-69-8  | EEATOX<br>Acute fish toxicity                     | Non-TSCA Protocol/Guideline (see docket# OPTS-42005) | Fathead minnow                                | static, 96 hr   | <0.0037 to 210 mg/L (5 concentrations/test material up to limit of solubility) | Not specified           | No acute toxicity below the limit of aqueous solubility.  | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0508481 |
| Butyl 2-ethylhexyl phthalate | 85-69-8  | EECTOX<br>Chronic daphnid toxicity                | Non-TSCA Protocol/Guideline (see docket# OPTS-42005) | <i>Daphnia magna</i>                          | flow-through, 21 days   | 0.015-80 mg/L (measured)   | Not specified           | Non-toxic.  | 50 FR 5421; 2/6/85<br>Fiche# OTS0508496       |
| Butyl 2-ethylhexyl phthalate | 85-69-8  | EFBDEG<br>Biodegradation study                    | Non-TSCA Protocol/Guideline (see docket# OPTS-42005) | Not applicable                                | shake flask, 28 d, CO by GC   | 4 mg carbon/equivalent   | Not applicable          | Primary biodegradation of 90% or higher and ultimate biodegradation of 55%.   | 48 FR 53159;<br>11/25/83<br>OTS0508481        |
| Butyl 2-ethylhexyl phthalate | 85-69-8  | EFBDEG<br>Biodegradation study                    | Non-TSCA Protocol/Guideline (see docket# OPTS-42005) | Not applicable                                | 23° C, 24 hr, CO <sub>2</sub> by GC                                 | 1 mg/L   | Not applicable          | Exhibited at least 50% primary degradation in 24 hours.   | 49 FR 44142; 11/2/84<br>Fiche# OTS0508490     |
| Butyl 2-ethylhexyl phthalate | 85-69-8  | EFCHEWSOL<br>Water solubility                     | Non-TSCA Protocol/Guideline (see docket# OPTS-42005) | Not applicable                                | deionized water; equilibrate for 24 hr at 25 ± 2° C; analysis by GC | Not specified  | Not applicable          | Solubility in distilled water = 2.69 ± 0.15 mg/L.   | 48 FR 34119; 7/27/83<br>Fiche# OTS0508479     |
| Butyl 2-ethylhexyl phthalate | 89-69-8  | EEATOX<br>Acute fish toxicity                     | Non-TSCA Protocol/Guideline (see docket# OPTS-42005) | Fathead minnow                                | flow-through, 96 hr   | 0.026-34 mg/L (measured)   | Not specified           | No acute toxicity below the limit of aqueous solubility.  | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0508481 |
| <i>p</i> -Phenylenediamine   | 106-50-3 | EEATOX<br>Acute fish toxicity (Voluntary test)    | Non-TSCA Protocol/Guideline                          | fathead minnow ( <i>Pimephales promelas</i> ) | static, 96 hr   | 0, 0.003, 0.007, 0.015, 0.03, 0.12, 0.25, 0.5, 1.0 mg/L (nominal)              | 20/group (10/replicate) | The test substance exhibited extreme acute toxicity to fathead minnows under static unaerated test conditions. At 0.12 mg/L and greater some fish exhibited clinical signs of toxicity including rapid respiration, swimming at the surface and darkening in color. The LC <sub>50</sub> was determined to be 0.057 mg/L. | 51 FR 6468; 2/24/86<br>Fiche# OTS0528712      |
| <i>p</i> -Phenylenediamine   | 106-50-3 | EEATOX<br>Acute aquatic toxicity (Voluntary test) | Non-TSCA Protocol/Guideline                          | <i>Daphnia magna</i>                          | static, 48 hr   | 0, 0.08, 0.1, 0.2, 0.3, 0.4, 0.6, 0.8, 1.0, 1.5, 2.0 mg/L (nominal)            | 20/group (10/replicate) | The test substance exhibited extreme acute toxicity to <i>Daphnia magna</i> under static unaerated test conditions. The LC <sub>50</sub> was determined to be 0.28 mg/L.  | 51 FR 6468; 2/24/86<br>Fiche# OTS0528712      |

## Results of Testing

| Chemical Name              | CAS No.  | Study Code/Type  | Protocol/Guideline              | Species                                | Exposure                                     | Dose/Concentration   | No. per Group     | Results   | Reference   |
|----------------------------|----------|--|---------------------------------|--|--|--|-------------------|---|---|
| <i>p</i> -Phenylenediamine | 106-50-3 | EEATOX<br>Acute fish toxicity                          | 40 CFR 797.1400                 | rainbow trout                          | flow-through, 96 hr                          | ranged from 0.061 to 16 mg/L (mean measured)   | 20 (10/replicate) | The 96-hour LC <sub>50</sub> was 3.9 (95% confidence limits = 3.1-5.0) mg/L.  | 55 FR 50055; 12/4/90<br>Fiche# OTS0528740                           |
| <i>p</i> -Phenylenediamine | 106-50-3 | EEATOX<br>Acute invertebrate toxicity                  | 40 CFR 795.120                  | <i>Gammarus fasciatus</i> (amphipod)   | flow-through, 96 hr                          | ranged from 1.9 to 9.7 mg/L (mean measured)  | 20 (10/replicate) | The 96-hour LC <sub>50</sub> was 8.1 (95% confidence limits = 7.1-9.4) mg/L.  | 56 FR 5688; 2/12/91<br>Fiche# OTS0533309                            |
| <i>p</i> -Phenylenediamine | 106-50-3 | EEATOX<br>Algae acute toxicity (Voluntary test)        | Non-TSCA Protocol/<br>Guideline | <i>Selenastrum capicornutum</i> (alga) | 96 hr  | Not specified  | Not applicable    | The LC <sub>50</sub> was determined to be 0.28 mg/L.  | 51 FR 6468; 2/24/86<br>Fiche# OTS0528712                            |
| <i>p</i> -Phenylenediamine | 106-50-3 | EECTOX<br>Daphnid life-cycle                           | 40 CFR 797.1330                 | <i>Daphnia magna</i>                   | flow-through, 21 days                        | 0.00204, 0.00834, 0.0252, 0.0709, 0.211, 0.419, 1.28 mg/L  | 10/replicate      | The 21 day EC <sub>50</sub> value was 0.0411 mg/L. The NOEC for immobility was 0.00834 mg/L. The NOEC for total neonates per surviving adult was 0.0709 mg/L. The NOEC for length in millimeters was 0.00204 mg/L.  | 58 FR 7784; 2/9/93,<br>Docket# OPPTS-44595                          |
| <i>p</i> -Phenylenediamine | 106-50-3 | EFADEG<br>Oxidation in water (Voluntary test)          | Non-TSCA Protocol/<br>Guideline | Not applicable                         | well water, 25 °C, 21 days                   | 2.5 and 25 mg/L  | Not applicable    | The oxidative half-life was determined to be 4.1 hours at 2.5 mg/L (k = 0.17 hr <sup>-1</sup> ) and 8.9 hours at 25 mg/L (k = 0.08 hr <sup>-1</sup> ). There was no statistically-significant difference in the degradation at 2.5 compared to 25 mg/L. In general, the test substance appears not to be refractory.  | 51 FR 6468; 2/24/86<br>Fiche# OTS0528712                            |
| <i>p</i> -Phenylenediamine | 106-50-3 | EFADEG<br>Oxidation in water (Voluntary test)          | Non-TSCA Protocol/<br>Guideline | Not applicable                         | river water, 25 °C                           | 0.56, 3.12, 6.20, 6.84, 6.55, 10.33 mg/L (aerated); 0.97, 4.73, 6.72, 8.64, 9.38, 10.33 mg/L (non-aerated) | Not applicable    | The oxidative half-lives were determined to be 4 hr (aerated) and 4.7 hr (non-aerated).   | 51 FR 6468; 2/24/86<br>Fiche# OTS0528712                            |
| <i>p</i> -Phenylenediamine | 106-50-3 | EFADEGPHOT<br>Indirect photolysis screening            | 40 CFR 795.70                   | Not applicable                         | distilled water, synthetic humic water, pH 7 | 1 - 10 ppm   | Not applicable    | The aqueous photolysis of the test substance was not enhanced by the presence of natural humic acid. The loss of the test substance was 1.6 times faster in the presence of humic acid than in distilled water.   | 55 FR 50055; 12/4/90,<br>55 FR 53348;<br>12/28/90 Fiche# OTS0528741 |
| <i>p</i> -Phenylenediamine | 106-50-3 | HENEUR<br>Functional observational battery, acute      | 40 CFR 798.6050 (modified)      | rats                                   | oral (gavage)                                | 0, 20, 40, 80 mg/kg/day  | 12/sex/group      | At all the levels tested females displayed significant dose related effects on body weight gain. Males demonstrated similar effects but only at the two higher doses. In terms of FOB assessments females demonstrated statistically significant dose related signs of general malaise (postural changes, palpebral closure, and decreased arousal). Males demonstrated similar responses but they were not statistically significant from controls. There is no evidence that the test substance exerted a primary effect on the nervous system. | 55 FR 50055; 12/4/90<br>Fiche# OTS0528739                           |
| <i>p</i> -Phenylenediamine | 106-50-3 | HENEUR<br>Functional observational battery, subchronic | 40 CFR 798.6050 (modified)      | rats                                   | gavage, 90 days                              | 4, 8, 16 mg/kg   | 10/sex            | No substance-related deaths were observed. Wet chin, inguen, and perineum were observed in animals at 16 mg/kg. No treatment-related effects were found in Functional observational battery. The NOEL was 8 mg/kg.  | 57 FR 33348; 7/28/92,<br>Docket# OPPTS-44589                        |

## Results of Testing

| Chemical Name               | CAS No.  | Study Code/Type                                     | Protocol/Guideline              | Species  | Exposure                 | Dose/Concentration  | No. per Group              | Results   | Reference   |
|-----------------------------|----------|---|---------------------------------|--|--------------------------|---|----------------------------|---|---|
| <i>p</i> -Phenylenediamine  | 106-50-3 | HENEUR<br>Motor activity, acute                     | 40 CFR 798.6200<br>(modified)   | rats   | oral (gavage)            | 0, 20, 40, 80 mg/kg/day   | 12/sex/group               | At all the levels tested females displayed significant dose related effects on body weight gain. Males demonstrated similar effects but only at the two higher doses. Dose-related motor activity decreases greater than those shown by controls were demonstrated, however, in the absence of other signs of neurological impairment, the motor activity response is interpreted as being indicative of general malaise at the levels tested. There is no evidence that the test substance exerted a primary effect on the nervous system. | 55 FR 50055; 12/4/90<br>Fiche# OTS0528739                         |
| <i>p</i> -Phenylenediamine  | 106-50-3 | HENEUR<br>Motor activity, subchronic                | 40 CFR 798.6200<br>(modified)   | rats   | gavage, 90 days          | 4, 8, 16 mg/kg  | 10/sex                     | No substance-related deaths were observed. Wet chin, inguen, and perineum were observed in animals at 16 mg/kg. No treatment-related effects on motor activity were observed. The NOEL was 8 mg/kg.   | 57 FR 33348; 7/28/92,<br>Docket# OPPTS-44589                      |
| <i>p</i> -Phenylenediamine  | 106-50-3 | HENEUR<br>Neuropathology, subchronic                | 40 CFR 798.6400                 | rats   | gavage, 90 days          | 4, 8, 16 mg/kg  | 10/sex                     | No substance-related deaths were observed. Wet chin, inguen, and perineum were observed in animals at 16 mg/kg. Neuropathology showed no treatment-related abnormalities and no ocular tissue effect. The NOEL was 8 mg/kg. No observed effect was considered neurotoxic.   | 57 FR 33348; 7/28/92,<br>Docket# OPPTS-44589                      |
| <i>m</i> -Phenylene-diamine | 108-45-2 | EEATOX<br>Acute fish toxicity (Voluntary test)      | Non-TSCA Protocol/<br>Guideline | fathead minnow<br>( <i>Pimephales promelas</i> ) | static, 96 hr            | 0, 750, 1000, 1300, 1800, 2400, 3200, 4200, 5600, 7500, 10,000 mg/L (nominal) | 20/group<br>(10/replicate) | The test substance exhibited extreme low acute toxicity to fathead minnows under static unaerated test conditions. At 1800 mg/L and greater some fish exhibited clinical signs including darkening in color, erratic swimming, lying on the bottom and swimming at the surface. The LC <sub>50</sub> was determined to be 1618 mg/L.  | 51 FR 6468; 2/24/86<br>Fiche# OTS0528712                          |
| <i>m</i> -Phenylene-diamine | 108-45-2 | EEATOX<br>Acute aquatic toxicity (Voluntary test)   | Non-TSCA Protocol/<br>Guideline | <i>Daphnia magna</i>                             | static, 48 hr            | 0, 1.0, 1.3, 1.8, 2.4, 3.2, 4.2, 5.6, 7.5, 10.0 mg/L (nominal)                | 20/group<br>(10/replicate) | The test substance exhibited moderate acute toxicity to <i>Daphnia magna</i> under static unaerated test conditions. The LC <sub>50</sub> was determined to be 5.9 mg/L.  | 51 FR 6468; 2/24/86<br>Fiche# OTS0528712                          |
| <i>m</i> -Phenylene-diamine | 108-45-2 | EEATOX<br>Acute fish toxicity                       | 40 CFR 797.1400                 | rainbow trout                                    | flow-through, 96 hr      | ranged from 107 to 1108 mg/L (mean measured)                                  | 20<br>(10/replicate)       | The 96-hour LC <sub>50</sub> was 512 (95% confidence limits = 466-561) mg/L.  | 55 FR 50055; 12/4/90,<br>56 FR 5688; 2/12/91<br>Fiche# OTS0533309 |
| <i>m</i> -Phenylene-diamine | 108-45-2 | EEATOX<br>Acute invertebrate toxicity               | 40 CFR 795.120                  | <i>Gammarus fasciatus</i><br>(amphipod)          | flow-through, 96 hr      | ranged from 3.8 to 23.4 mg/L (mean measured)                                  | 20<br>(10/replicate)       | The 96-hour LC <sub>50</sub> was 4.6 (95% confidence limits = 4.3-5.1) mg/L.  | 56 FR 5688; 2/12/91<br>Fiche# OTS0533309                          |
| <i>m</i> -Phenylene-diamine | 108-45-2 | EEATOX<br>Algae acute toxicity (Voluntary test)     | Non-TSCA Protocol/<br>Guideline | <i>Selenastrum capicornutum</i><br>(alga)        | 96 hr                    | Not specified   | Not applicable             | The LC <sub>50</sub> was determined to be 2.4 mg/L.   | 51 FR 6468; 2/24/86<br>Fiche# OTS0528712                          |
| <i>m</i> -Phenylene-diamine | 108-45-2 | EECTOX<br>Chronic aquatic toxicity (Voluntary test) | Non-TSCA Protocol/<br>Guideline | <i>Daphnia magna</i>                             | continuous-flow, 21 days | 0.1, 0.2, 0.4, 0.75, 1.5, 3.0 mg/L  | 20/group<br>(10/replicate) | Reproduction (number of young/day and total young produced) was the most sensitive indicator of the toxicity of the test substance to <i>Daphnia magna</i> , where the NOEL was determined to be 0.2 mg/L. A NOEL for growth of 1.5 mg/L was determined. Survival was the least sensitive indicator. The Maximum Allowable Toxicant Concentration (MATC) is between 0.2 and 0.4 mg/L.   | 51 FR 6468; 2/24/86<br>Fiche# OTS0528712                          |

## Results of Testing

| Chemical Name               | CAS No.  | Study Code/Type  | Protocol/Guideline              | Species                            | Exposure   | Dose/Concentration           | No. per Group  | Results   | Reference  |
|-----------------------------|----------|--|---------------------------------|------------------------------------|--|------------------------------|----------------|---|--|
| <i>m</i> -Phenylene-diamine | 108-45-2 | EFADEG<br>Oxidation in water<br>(Voluntary test)               | Non-TSCA Protocol/<br>Guideline | Not applicable                     | well water, 25 °C,<br>21 days                      | 2.5 and 25 mg/L              | Not applicable | The oxidative half-life was determined to be 13.4 days at 2.5 mg/L ( $k = 0.05 \text{ d}^{-1}$ ) and 33.6 days at 25 mg/L ( $k = 0.02 \text{ d}^{-1}$ ). Results indicate that higher concentrations of the test substance may be slightly resistant to degradation under these test conditions. In general, the test substance appears not to be refractory.   | 51 FR 6468; 2/24/86<br>Fiche# OTS0528712                               |
| <i>m</i> -Phenylene-diamine | 108-45-2 | EFADEGPHOT<br>Indirect photolysis<br>screening                 | 40 CFR 795.70                   | Not applicable                     | distilled water,<br>synthetic humic water,<br>pH 7 | 1 - 10 ppm                   | Not applicable | The aqueous photolysis of the test substance was significantly enhanced by the presence of natural humic acid. The rate constants for the indirect photolysis were found to be $0.86 \text{ d}^{-1}$ . The loss of the test substance was considerably faster in the distilled water. The test substance is very photolabile. Maximum rate constants of 0.34, 0.50, 0.18, 0.069 $\text{d}^{-1}$ and photolysis half-lives of 2.0, 1.4, 3.8, and 10 days for spring, summer, fall, and winter, respectively.   | 55 FR 50055; 12/4/90,<br>55 FR 53348;<br>12/28/90 Fiche#<br>OTS0528741 |
| <i>m</i> -Phenylene-diamine | 108-45-2 | HEGTOXCHRM<br>Mammalian bone<br>marrow micronucleus<br>assay   | 40 CFR 798.5395                 | mice                               | oral (gavage), 2 x, 24<br>hr apart                 | 0, 16, 33, 65 mg/kg/dose     | 3/sex          | <i>m</i> -Phenylenediamine did not induce micronuclei, but a significant depression in the ratio of young, polychromatic erythrocytes to mature, normochromatic erythrocytes was noted in high-dose males at the 48-hour sampling interval.   | 56 FR 5688; 2/12/91<br>Fiche# OTS0533308                               |
| <i>m</i> -Phenylene-diamine | 108-45-2 | HEGTOXMUTA<br>Sex-linked recessive<br>lethal assay             | 40 CFR 798.5275                 | <i>Drosophila<br/>melanogaster</i> | injection  | 0.3 µL at 10,000 ppm         | Not specified  | The test substance is equivocal with respect to its ability to induce mutations in the post-meiotic germ cells of fruit flies when administered by injection to adult males. The sex-linked recessive lethal results was determined to be 29/22189 (0.131%).  | 56 FR 22715; 5/16/91<br>Fiche# OTS0533310                              |
| <i>m</i> -Phenylene-diamine | 108-45-2 | HENEUR<br>Functional observa-<br>tional battery, acute         | 40 CFR 798.6050<br>(modified)   | rats                               | oral (gavage)                                      | 0, 75, 150, 300<br>mg/kg/day | 12/sex/group   | The test substance demonstrated toxicity at all dose levels. Females appeared to be generally more sensitive to the systemic toxicity effects observed than males. Those effects included reduced body weight gain, reduced feed consumption and certain FOB parameters. On the day of dosing, FOB assessments detected palpebral closure in the majority of both sexes. Grip strength (forelimb and hind limb) and foot splay measures were not affected. The general malaise encountered was accompanied in some cases by postural changes, decreased arousal, gait alterations and breathing. There is no evidence that the test substance exerted a primary effect on the nervous system. | 55 FR 50055; 12/4/90<br>Fiche# OTS0528739                              |
| <i>m</i> -Phenylene-diamine | 108-45-2 | HENEUR<br>Functional observa-<br>tional battery,<br>subchronic | 40 CFR 798.6050<br>(modified)   | rats                               | gavage, 90 days                                    | 5, 10, 20 mg/kg              | 10/sex         | No mortality was observed. Lethargy and salivation were observed at 10 and 20 mg/kg. Reduction in weight gain and feed efficiency were observed at 20 mg/kg. Decreased hindlimb grip strength in females was observed at 20mg/kg. The NOEL was 5mg/kg.  | 57 FR 33348; 7/28/92,<br>Docket# OPPTS-<br>44589                       |

## Results of Testing

| Chemical Name              | CAS No.  | Study Code/Type                                   | Protocol/Guideline              | Species                                       | Exposure              | Dose/Concentration                                      | No. per Group           | Results  | Reference                                    |
|----------------------------|----------|---|---------------------------------|---|-----------------------|---|-------------------------|--|--|
| <i>m</i> -Phenylenediamine | 108-45-2 | HENEUR<br>Motor activity, acute                   | 40 CFR 798.6200 (modified)      | rats  | oral (gavage)         | 0, 75, 150, 300 mg/kg/day                               | 12/sex/group            | The test substance demonstrated toxicity at all dose levels. Females appeared to be generally more sensitive to the systemic toxicity effects observed than males. Those effects included reduced body weight gain, reduced feed consumption and certain MAT parameters. Grip strength (forelimb and hind limb) and foot splay measures were not affected. The general malaise encountered was accompanied in some cases by postural changes, decreased arousal, gait alterations and breathing. While the extent and duration of these and the motor activity changes were found to be generally dose related, motor activity response was interpreted to be attributal primarily to general malaise resulting from systemic toxicity. There is no evidence that the test substance exerted a primary effect on the nervous system. | 55 FR 50055; 12/4/90<br>Fiche# OTS0528739    |
| <i>m</i> -Phenylenediamine | 108-45-2 | HENEUR<br>Motor activity, subchronic              | 40 CFR 798.6200 (modified)      | rats  | gavage, 90 days       | 5, 10, 20 mg/kg   | 10/sex                  | No mortality was observed. Lethargy and salivation were observed at 10 and 20 mg/kg. Reduction in weight gain and feed efficiency were observed at 20 mg/kg. Reduction in vertical and horizontal motor activity counts were found at 10 and 20 mg/kg. The NOEL was 5 mg/kg.   | 57 FR 33348; 7/28/92,<br>Docket# OPPTS-44589 |
| <i>m</i> -Phenylenediamine | 108-45-2 | HENEUR<br>Neuropathology, subchronic              | 40 CFR 798.6400                 | rats  | gavage, 90 days       | 5, 10, 20 mg/kg   | 10/sex                  | No mortality was observed. Lethargy and salivation were observed at 10 and 20 mg/kg. Reduction in weight gain and feed efficiency were found at 20 mg/kg. Neuropathology revealed no treatment-related abnormalities and no ocular tissue effect. The NOEL was 5 mg/kg. No observed effect was considered neurotoxic   | 57 FR 33348; 7/28/92,<br>Docket# OPPTS-44589 |
| <i>o</i> -Phenylenediamine | 95-54-5  | EEATOX<br>Acute aquatic toxicity (Voluntary test) | Non-TSCA Protocol/<br>Guideline | <i>Daphnia magna</i>                          | static, 48 hr         | 0, 0.3, 0.4, 0.6, 0.8, 1.0, 1.5, 2, 3, 4 mg/L (nominal) | 20/group (10/replicate) | The test substance exhibited high acute toxicity to <i>Daphnia magna</i> under static unaerated test conditions. The LC <sub>50</sub> was determined to be 0.88 mg/L.  | 51 FR 6468; 2/24/86<br>Fiche# OTS0528712     |
| <i>o</i> -Phenylenediamine | 95-54-5  | EEATOX<br>Acute fish toxicity (Voluntary test)    | Non-TSCA Protocol/<br>Guideline | fathead minnow ( <i>Pimephales promelas</i> ) | static, 96 hr         | 0, 10, 15, 20, 25, 35, 45, 60, 75, 100 mg/L (nominal)   | 20/group (10/replicate) | The test substance exhibited moderate acute toxicity to fathead minnows under static unaerated test conditions. At 45 mg/L and greater some fish exhibited clinical signs including erratic swimming, swimming at the surface, lying on the bottom, lethargy, partial loss of equilibrium and gasping for air. The LC <sub>50</sub> was determined to be 0.44 mg/L.  | 51 FR 6468; 2/24/86<br>Fiche# OTS0528712     |
| <i>o</i> -Phenylenediamine | 95-54-5  | EEATOX<br>Acute fish toxicity                     | 40 CFR 797.1400                 | rainbow trout                                 | flow-through, 96 hr   | ranged from 6.8 to 210 mg/L (mean measured)             | 20 (10/replicate)       | The 96-hour LC <sub>50</sub> was 42.9 (95% confidence limits = 35.4-52.5) mg/L.  | 55 FR 50055; 12/4/90<br>Fiche# OTS0528740    |
| <i>o</i> -Phenylenediamine | 95-54-5  | EEATOX<br>Acute invertebrate toxicity             | 40 CFR 795.120                  | <i>Gammarus fasciatus</i> (amphipod)          | flow-through, 96 hr   | ranged from 4.1 to 23.2 mg/L (mean measured)            | 20 (10/replicate)       | The 96-hour LC <sub>50</sub> was 9.1 (95% confidence limits = 8.0 - 10.5) mg/L.  | 56 FR 5688; 2/12/91<br>Fiche# OTS0533309     |
| <i>o</i> -Phenylenediamine | 95-54-5  | EEATOX<br>Algae acute toxicity (Voluntary test)   | Non-TSCA Protocol/<br>Guideline | <i>Selenastrum capricornutum</i> (alga)       | 96 hr                 | Not specified   | Not applicable          | The LC <sub>50</sub> was determined to be 0.16 mg/L.   | 51 FR 6468; 2/24/86<br>Fiche# OTS0528712     |
| <i>o</i> -Phenylenediamine | 95-54-5  | EECTOX<br>Daphnid life-cycle                      | 40 CFR 797.1330                 | <i>Daphnia magna</i>                          | flow-through, 21 days | 0.018, 0.084, 0.38 mg/L                                 | 10/replicate            | The 21-day EC <sub>50</sub> was 0.28 mg/L. The MATC was 0.18 mg/L. The NOEC was 0.084 mg/L.  | 58 FR 9174; 2/19/93,<br>Docket# OPPTS-44596  |

## Results of Testing

| Chemical Name              | CAS No. | Study Code/Type  | Protocol/Guideline              | Species        | Exposure   | Dose/Concentration            | No. per Group  | Results  | Reference  |
|----------------------------|---------|--|---------------------------------|----------------|--|-------------------------------|----------------|--|--|
| <i>o</i> -Phenylenediamine | 95-54-5 | EFADEG<br>Oxidation in water<br>(Voluntary test)               | Non-TSCA Protocol/<br>Guideline | Not applicable | well water, 25 °C<br>21 days                       | 2.5 and 25 mg/L               | Not applicable | The oxidative half-life was determined to be 2.7 days at 2.5 mg/L ( $k = 0.26 \text{ d}^{-1}$ ) and 4.5 days at 25 mg/L ( $k = 0.16 \text{ d}^{-1}$ ). There was no statistically significant difference in the degradation at 2.5 compared to 25 mg/L. In general, the test substance appears not to be refractory.   | 51 FR 6468; 2/24/86<br>Fiche# OTS0528712                               |
| <i>o</i> -Phenylenediamine | 95-54-5 | EFADEGPHOT<br>Indirect photolysis<br>screening                 | 40 CFR 795.70                   | Not applicable | distilled water,<br>synthetic humic water,<br>pH 7 | 1 - 10 ppm                    | Not applicable | The aqueous photolysis of the test substance was approximately $6.0 \text{ d}^{-1}$ in both distilled water and humic acid. No significant difference between reactions in distilled water and synthetic humic water. The test substance was determined to be very photolabile.  | 55 FR 50055; 12/4/90,<br>55 FR 53348;<br>12/28/90 Fiche#<br>OTS0528741 |
| <i>o</i> -Phenylenediamine | 95-54-5 | HENEUR<br>Functional observa-<br>tional battery, acute         | 40 CFR 798.6050<br>(modified)   | rats           | oral (gavage)                                      | 0, 225, 450, 900<br>mg/kg/day | 12/sex/group   | At all the levels tested the test substance produced systemic toxicity which caused dose-related malaise. Significant body weight losses were observed as well as sharply decreased feed consumption. The general malaise, demonstrated by a majority of the animals with postural changes, partial or entirely closed eyes and decreased arousal. Neither forelimb or hind limb grip strength, or foot splay were affected by treatment. There is no evidence that the test substance exerted a primary effect on the nervous system.   | 55 FR 50055; 12/4/90<br>Fiche# OTS0528739                              |
| <i>o</i> -Phenylenediamine | 95-54-5 | HENEUR<br>Functional observa-<br>tional battery,<br>subchronic | 40 CFR 798.6050<br>(modified)   | rats           | gavage, 90 days                                    | 20, 40, 80 mg/kg              | 10/sex         | No substance-related deaths were observed. Decreased body weight gain, reduced feed efficiency, slight palpebral closure, enhanced tail pinch responses, soiled fur, and yellow staining of perineum, inguen, abdomen, and underbody were observed at 80 mg/kg. No treatment-related effects were seen in the Functional observational battery. The NOEL was 40 mg/kg.   | 57 FR 33348; 7/28/92,<br>Docket# OPPTS-<br>44589                       |
| <i>o</i> -Phenylenediamine | 95-54-5 | HENEUR<br>Motor activity, acute                                | 40 CFR 798.6200<br>(modified)   | rats           | oral (gavage)                                      | 0, 225, 450, 900<br>mg/kg/day | 12/sex/group   | At all the levels tested the test substance produced systemic toxicity which caused dose-related malaise. Significant body weight losses were observed as well as sharply decreased feed consumption. The general malaise, demonstrated by a majority of the animals with postural changes, partial or entirely closed eyes and decreased arousal. Neither forelimb or hind limb grip strength, or foot splay were affected by treatment. Motor activity was dramatically influenced as a function of dose. There is no evidence that the test substance exerted a primary effect on the nervous system. | 55 FR 50055; 12/4/90<br>Fiche# OTS0528739                              |
| <i>o</i> -Phenylenediamine | 95-54-5 | HENEUR<br>Motor activity,<br>subchronic                        | 40 CFR 798.6200<br>(modified)   | rats           | gavage, 90 days                                    | 20, 40, 80 mg/kg              | 10/sex         | No substance-related deaths were observed. Decreased body weight gain, reduced feed efficiency, slight palpebral closure, enhanced tail pinch responses, soiled fur, and yellow staining of perineum, inguen, abdomen, and underbody were found at 80 mg/kg. The NOEL was 40 mg/kg.  | 57 FR 33348; 7/28/92,<br>Docket# OPPTS-<br>44589                       |

## Results of Testing

| Chemical Name              | CAS No. | Study Code/Type  | Protocol/Guideline         | Species           | Exposure   | Dose/Concentration              | No. per Group | Results  | Reference  |
|----------------------------|---------|--|----------------------------|-------------------|--|---------------------------------|---------------|--|--|
| <i>o</i> -Phenylenediamine | 95-54-5 | HENEUR<br>Neuropathology,<br>subchronic                          | 40 CFR 798.6400            | rats              | gavage, 90 days                                    | 20, 40, 80 mg/kg                | 10/sex        | No substance-related deaths were observed. Decreased body weight gain, reduced feed efficiency, slight palpebral closure, enhanced tail pinch responses, soiled fur, and yellow staining of perineum, inguen, abdomen, and underbody were observed at 80 mg/kg. Neuropathology revealed no treatment-related abnormalities and no ocular tissue effects. The NOEL was 40 mg/kg. No observed effect was considered neurotoxic except pinch tail at 80 mg/kg.  | 57 FR 33348; 7/28/92, Docket# OPPTS-44589                    |
| Methyl Ethyl Ketoxime      | 96-29-7 | HECTOXCARC<br>Oncogenicity study                                 | 40 CFR 798.3300            | rats              | whole-body inhalation, 6 hr/day, 5 d/wk, 26 months | 0, 15, 75, 375 ppm              | 80/sex/group  | There were no differences in survival among any of the exposure groups including the control. An increased incidence of hepatocellular carcinoma and adenoma and spongiosis hepatitis was reported. Under the exposure conditions of this study, the test substance was a liver oncogen in the male rat at 75 ppm.   | 59 FR 23061; 5/4/94 Fiche# OTS0527778-4, Docket# OPPTS-44608 |
| Methyl Ethyl Ketoxime      | 96-29-7 | HECTOXCARC<br>Oncogenicity study                                 | 40 CFR 798.3300            | mice              | whole-body inhalation, 6 hr/day, 5d/wk, 18 months  | 15, 75, 375 ppm                 | 60/sex/group  | MEKO produced changes in the olfactory epithelium in all exposed groups in both sexes and was a liver oncogen in males at 375 ppm.   | 58 FR 65353; 12/14/93, Docket# OPPTS-44603                   |
| Methyl Ethyl Ketoxime      | 96-29-7 | HEGTOXCHRM<br>Mammalian bone marrow chromosomal aberration assay | 40 CFR 798.5385 (modified) | rats              | oral (gavage), single dose                         | 300, 600, 1200 mg/kg            | 5/sex         | No increase in chromosomal aberrations was seen.   | 56 FR 2924; 1/25/91 Fiche# OTS0529840                        |
| Methyl Ethyl Ketoxime      | 96-29-7 | HEGTOXMUTA<br>Sex linked recessive lethal assay                  | 40 CFR 798.5275            | <i>Drosophila</i> | oral (feeding), 3 days                             | 7500 ppm in 5% sucrose solution | 15 males      | No increase in mutations was observed.   | 56 FR 22715; 5/16/91 Fiche# OTS0529843                       |
| Methyl Ethyl Ketoxime      | 96-29-7 | HENEUR<br>Neuropathology   | 40 CFR 798.6400 (modified) | rats              | oral (gavage), 5 d/wk, 13 wks                      | 0, 40, 125, 400 mg/kg/d         | 10 or 14/sex  | No changes were noted in nervous system structure, but organ (liver and spleen) weights were altered.  | 56 FR 22715; 5/16/91 Fiche# OTS0529843                       |
| Methyl Ethyl Ketoxime      | 96-29-7 | HENEUR<br>Motor activity   | 40 CFR 798.6200 (modified) | rats              | oral (gavage), 5 d/wk, 13 wks                      | 0, 40, 125, 400 mg/kg/d         | 10 or 14/sex  | No statistically significant treatment-related changes were noted in total activity counts, but mean total activity counts in the high-dose group was lower than controls.   | 56 FR 22715; 5/16/91 Fiche# OTS0529843                       |
| Methyl Ethyl Ketoxime      | 96-29-7 | HENEUR<br>Functional observational battery                       | 40 CFR 798.6050 (modified) | rats              | oral (gavage), 5 d/wk, 13 wks                      | 0, 40, 125, 400 mg/kg/d         | 10 or 14/sex  | No treatment-related changes were noted on survival or body weights. Dose-dependent decreases were seen in hemoglobin values, hematocrit, and red blood cell counts in all treated groups, along with increased methemoglobin values, white blood cells, lymphocytes, and Heinz body counts. Treatment-related transient increased incidence of the following were noted in high-dose rats: easy removal and handling, slightly to moderately impaired gait, aerial righting reflex, and slower approach response. | 56 FR 22715; 5/16/91 Fiche# OTS0529843                       |
| Methyl Ethyl Ketoxime      | 96-29-7 | HENEUR<br>Functional observational battery                       | 40 CFR 798.6050 (modified) | rats              | oral (gavage), single dose                         | 100, 300, 900 mg/kg             | 10/sex        | No mortalities or changes in body weight, food consumption, clinical observations, or gross pathology were noted. Transient effects were noted in mid- and high-dose rats in gait, aerial righting reflex, easy removal, and handling. No consistent behavioral effects were observed in low-dose rats.  | 56 FR 22715; 5/16/91 Fiche# OTS0529842                       |
| Methyl Ethyl Ketoxime      | 96-29-7 | HENEUR<br>Motor activity   | 40 CFR 798.6200 (modified) | rats              | oral (gavage), single dose                         | 100, 300, 900 mg/kg             | 10/sex        | Significant depressions in motor activity were seen in high-dose rats at the 1-hour post-dose assessment. Thereafter, all observations were comparable to controls.  | 56 FR 22715; 5/16/91 Fiche# OTS0529842                       |

## Results of Testing

| Chemical Name         | CAS No. | Study Code/Type                           | Protocol/Guideline                                     | Species | Exposure  | Dose/Concentration       | No. per Group | Results  | Reference                                 |
|-----------------------|---------|---|--|---------|---|--------------------------|---------------|--|---|
| Methyl Ethyl Ketoxime | 96-29-7 | HERTOXTERA Developmental toxicity         | 40 CFR 798.4900  | rats    | oral (gavage), gestation day 6 through 15               | 0, 60, 200, 600 mg/kg/d  | 25 females    | Maternal toxicity (clinical signs and decreased body weight and food consumption) occurred at 200 mg/kg/day and higher. No evidence of developmental toxicity or teratogenicity was noted at any level.  | Fiche# OTS0529841                         |
| Methyl Ethyl Ketoxime | 96-29-7 | HERTOXTERA Developmental toxicity         | 40 CFR 798.4900  | rabbits | oral (gavage), gestation day 6 through 18               | 0, 8, 14, 24, 40 mg/kg/d | 18 females    | Three high-dose females aborted and 8 were found dead between gestation days 11 and 24. Dose-related weight loss was noted at 24 and 40 mg/kg/day. An accurate assessment of developmental effects could not be made in the remaining high-dose group. The maternal NOEL was 14 mg/kg/day, and the embryotoxicity, fetotoxicity, and teratogenicity NOEL was 24 mg/kg/day.   | Fiche# OTS0529841                         |
| Methyl Ethyl Ketoxime | 96-29-7 | HERTOXTERE Reproductive/fertility effects | 40 CFR 798.4700 (modified)                             | rats    | oral (gavage), 10 wks pre-mating, through 2 generations | 0, 10, 100, 200 mg/kg/d  | 30/sex/dose   | Dose-related effects were seen in adults of both generations (reduced weight gain, extramedullary hematopoiesis, and hemosiderosis at 10 mg/kg/d). No evidence of reproductive or postnatal toxicity was noted.  | 57 FR 17907; 4/28/92<br>Fiche# OTS0540332 |
| Methyl Ethyl Ketoxime | 96-29-7 | HESTOX Inhalation toxicity                | Non-TSCA Protocol/ Guideline (see docket# OPTS-42099A) | rats    | inhalation; 6 hr/d, 5 d/wk, 4 weeks                     | 0, 25, 100, 500 ppm      | 10/sex/dose   | There were no mortalities or treatment-related physical effects. Exposure produced increases in methemoglobin levels in the 100 ppm group from 0.1 to 0.3% (females only) and in the 400 ppm group from 0.2 to 0.7% (both sexes). Significant alterations in the hematological parameters were also seen in the rats at 400 ppm. In addition, at 400 ppm, increased organ weights were seen in the liver and spleen.                           | Docket# OPTS-42099A<br>Received 6/1/91    |
| Methyl Ethyl Ketoxime | 96-29-7 | HESTOX Inhalation toxicity                | Non-TSCA Protocol/ Guideline (see docket# OPTS-42099A) | rats    | inhalation; 6 hr/d, 5 d/wk, 4 weeks                     | 0, 25, 100, 500 ppm      | 10/sex/dose   | Body weights were considerably decreased in both sexes at 300 ppm. Body weights were also decreased in males at 100 and 300 ppm. No significant differences in body weights were observed in F <sub>0</sub> or F <sub>1</sub> females exposed to 30 or 100 ppm. Neonatal survival and growth among F <sub>0</sub> and F <sub>1</sub> litters were not significantly different from their control groups. Fertility was unaffected by exposure. | Docket# OPTS-42099A<br>Received 6/1/91    |
| Methyl Ethyl Ketoxime | 96-29-7 | HESTOX Inhalation toxicity                | Non-TSCA Protocol/ Guideline (see docket# OPTS-42099A) | rats    | inhalation, whole-body; 6 hr/d, 5 d/wk, 13 weeks        | 0, 3, 10, 30, 100 ppm    | 80 males/dose | At the end of 1, 2, 4, and 13 week exposure periods, degeneration of olfactory epithelium lining of the dorsal meatus was seen in the anterior region of the nasal cavity. The incidence and severity was dose-related and greatest at 100 ppm followed by 30 ppm. At the end of the 13-week exposure period, this effect was also seen in several mice of the 10 ppm group. The NOEL was determined to be 3 ppm for olfactory degeneration.   | Docket# OPTS-42099A; 8/24/95              |
| Methyl Ethyl Ketoxime | 96-29-7 | HESTOX Inhalation probe study             | Non-TSCA Protocol/ Guideline (see docket# OPTS-42099A) | rats    | inhalation, 6 hr/d, 5 d/wk, 8 wks                       | 100 ppm                  | 10/sex        | One rat died on test day 44. Treatment-related decreased activity, prostration, and irregular gait were noted. Lacrimation and yellow anogenital staining in females was also noted.   | 56 FR 22715; 4/16/91<br>Fiche# OTS0529842 |
| Methyl Ethyl Ketoxime | 96-29-7 | HESTOX Inhalation probe study             | Non-TSCA Protocol/ Guideline (see docket# OPTS-42099A) | mice    | inhalation, 6 hr/d, 5 d/wk, 8 wks                       | 100 ppm                  | 10/sex        | Two mice died (test day 16 and 17). Treatment-related decreased activity, prostration and irregular gait were noted. Lacrimation and yellow anogenital staining in females was also noted. Mice appeared less sensitive than rats.   | 56 FR 22715; 4/16/91<br>Fiche# OTS0529842 |



## Results of Testing

| Chemical Name      | CAS No.  | Study Code/Type  | Protocol/Guideline   | Species        | Exposure  | Dose/Concentration                                  | No. per Group  | Results   | Reference   |
|--------------------|----------|--|--|----------------|---|---|----------------|---|---|
| 4-Vinylcyclohexene | 100-40-3 | EFTSPTVOLZ<br>Volatilization                                       | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42116) | Not applicable | ambient temperature,<br>solution stirred at<br>different rates. | 25 ppm  | Not applicable | The ratio the volatilization rate constant, $k'$ , to the reoxygenation rate constant, $k^o$ , was determined to be $0.50 \pm 0.10$ . $k'/k^o$ was found to be constant over a wide range of liquid turbulence ( $k^o$ ranging from 3 to 15 h <sup>-1</sup> ).  | 57 FR 37541; 7/15/92,<br>Docket# OPPTS-44590                        |
| 4-Vinylcyclohexene | 100-40-3 | HEADME<br>Pharmacokinetics<br>study: <i>in vitro</i><br>metabolism | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42116) | mice (female)  | <i>In-vitro</i>   | 0.01, 0.06, 0.24 mM                                 | Not applicable | Microsomal preparations from liver, lung, and ovaries were tested for their ability to metabolize 4-VCH and its epoxide metabolites. The reaction of 4-VCH to 4-VCH-1,2-epoxide proceeded at a detectable rate in mouse liver and lung. No reaction product was detected in mouse ovary. The balance of activation versus detoxification reactions in rats and mice indicates that the mouse may be more susceptible to 4-VCH toxicity resulting from epoxide metabolites. In general, the mouse was more efficient at metabolism of 4-VCH to epoxides, than was the rat, and the reaction had a greater $V_{max}/K_m$ ratio for epoxide formation.                                       | 58 FR 21302; 4/20/93,<br>58FR57602 10/26/93,<br>Docket# OPPTS-44602 |
| 4-Vinylcyclohexene | 100-40-3 | HEADME<br>Pharmacokinetics<br>study: <i>in vitro</i><br>metabolism | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42116) | rats (female)  | <i>In-vitro</i>   | 0.01, 0.06, 0.24 mM                                 | Not applicable | Microsomal preparations from liver, lung, and ovaries were tested for their ability to metabolize 4-VCH and its epoxide metabolites. The reaction of 4-VCH to 4-VCH-1,2-epoxide proceeded at a detectable rate in rat liver and lung. No reaction product was detected in rat ovary. The balance of activation versus detoxification reactions in rats and mice indicates that the mouse may be more susceptible to 4-VCH toxicity resulting from epoxide metabolites. In general, the rat may be more efficient at hydrolysis of epoxides than the mouse. Thus, the rat would tend to produce a lower concentration of epoxide metabolites than the mouse, given an equal dose of 4-VCH. | 58 FR 21302; 4/20/93,<br>58FR57602 10/26/93,<br>Docket# OPPTS-44602 |
| 4-Vinylcyclohexene | 100-40-3 | HEADME<br>Pharmacokinetics<br>study: partitioning                  | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42116) | rats (female)  | <i>In-vitro</i> , 37 °C for 3<br>hours                          | 750 to 2000 ppm in a<br>Teflon gas sampling<br>bag. | Not applicable | 4-VCH had a blood:air partition coefficient of 16.7 in rats. Other partition coefficients for 4-VCH were 20.0 for rat muscle:air. In general, the test compound was more soluble in fatty tissues than in lean tissues. Partition coefficients for the ovary were relatively high.  | 58 FR 21302; 4/20/93,<br>Docket# OPPTS-44597                        |
| 4-Vinylcyclohexene | 100-40-3 | HEADME<br>Pharmacokinetics<br>study: partitioning                  | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42116) | mice (female)  | <i>In-vitro</i> , 37 °C for 3<br>hours                          | 750 to 2000 ppm in a<br>Teflon gas sampling<br>bag. | Not applicable | 4-VCH had a blood:air partition coefficient of 20.1 in mice. Other partition coefficients for 4-VCH were 898.8 for mouse fat:air. In general, the test compound was more soluble in fatty tissues than in lean tissues. Partition coefficients for the ovary were relatively high.  | 58 FR 21302; 4/20/93,<br>Docket# OPPTS-44597                        |
| 4-Vinylcyclohexene | 100-40-3 | HEGTOXCHRM<br>Mammalian bone<br>marrow micronucleus<br>screen      | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42116) | mice           | inhalation, 6 hr/d, 5<br>d/wk, 13 weeks                         | 50, 250, 1000 ppm                                   | 5/sex          | No statistically significant increases in micronucleated polychromatic erythrocytes were observed at any 4-VCH concentration tested. No significant decrease in the ratio of young polychromatic erythrocytes to mature normochromatic erythrocytes was observed.   | 58 FR 57602<br>10/26/93, Docket#<br>OPPTS-44602                     |
| 4-Vinylcyclohexene | 100-40-3 | HEGTOXCHRM<br>Mammalian bone<br>marrow micronucleus<br>screen      | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42116) | rats           | inhalation, 6 hr/d, 5<br>d/wk, 13 weeks                         | 250, 1000, 1500 ppm                                 | 5/sex          | No statistically significant increases in micronucleated polychromatic erythrocytes were observed at any 4-VCH concentration tested. No significant decrease in the ratio of young polychromatic erythrocytes to mature normochromatic erythrocytes was observed.   | 58 FR 57602<br>10/26/93, Docket#<br>OPPTS-44602                     |

## Results of Testing

| Chemical Name      | CAS No.   | Study Code/Type                               | Protocol/Guideline                                   | Species              | Exposure  | Dose/Concentration                                 | No. per Group     | Results  | Reference                                  |
|--------------------|-----------|---|--|----------------------|---|--|-------------------|--|--|
| 4-Vinylcyclohexene | 100-40-3  | HESTOX<br>Subchronic inhalation toxicity      | Non-TSCA Protocol/Guideline (see docket #OPTS-42116) | rats                 | inhalation, 6 hr/d, 5 d/wk, 2 wks   | 0, 250, 750, 1500 ppm (nominal)                    | 5/sex/group       | One rat in the 750 ppm group died during the study. Significant body weight decreases in males exposed to 1500 ppm were evident. The no-observable-effect-level (NOEL) was 1500 ppm for both sexes.  | 59 FR 17101; 4/11/94, Fiche# OTS0556756    |
| 4-Vinylcyclohexene | 100-40-3  | HESTOX<br>Subchronic inhalation toxicity      | Non-TSCA Protocol/Guideline (see docket #OPTS-42116) | mice                 | inhalation, 6 hr/d, 5 d/wk, 2 wks   | 0, 250, 750, 1500 ppm (nominal)                    | 5/sex/group       | In the 1500 ppm group, 9/10 mice died during the study. There were 5/5 males and 4/5 females dead prior to exposure on test day 4. The 5th female was moribund and sacrificed. Clinical signs in both sexes following exposure on test day 3 included tremors, rapid breathing, lethargy, hunched-over posture, and closed eyes. Body weights were decreased in both sexes prior to death. The no-observable-effect-level (NOEL) was 750 ppm for both sexes. | 59 FR 17101; 4/11/94, Fiche# OTS0556756    |
| Crotonaldehyde     | 4170-30-3 | EEATOX<br>Daphnid acute toxicity              | 40 CFR 797.1300 (modified)                           | <i>Daphnia magna</i> | flow-through, 48 hr   | 0.6, 1.2, 2.5, 5, 10 mg/L                          | 20 (10/replicate) | The 48-hour EC <sub>50</sub> (immobilization) was 2.0 mg/L, and the NOEC was 0.61 mg/L.  | 55 FR 50055; 10/31/90<br>Fiche# OTS0530892 |
| Crotonaldehyde     | 4170-30-3 | EEATOX<br>Algae acute toxicity                | 40 CFR 797.1050 (modified)                           | freshwater alga      | closed-system culture flasks, 96 hr   | 2.7, 5.2, 10.6 mg/L (nominal)                      | Not applicable    | The 96-hour EC <sub>50</sub> (population growth) value was <0.881 mg/L. Crotonaldehyde was algicidal at 5.2 and 10.6 mg/L.   | 55 FR 50055; 10/31/90<br>Fiche# OTS0530892 |
| Crotonaldehyde     | 4170-30-3 | EEATOX<br>Acute invertebrate toxicity         | 40 CFR 797.1310 (modified)                           | Gammarus             | flow-through, 96 hr   | 0.6, 1.2, 2.5, 5, 10 mg/L                          | 20 (10/replicate) | The 96-hour LC <sub>50</sub> was 2.6 mg/L, and the NOEC was 1.1 mg/L.  | 55 FR 50055; 10/31/90<br>Fiche# OTS0530892 |
| Crotonaldehyde     | 4170-30-3 | EEATOX<br>Acute fish toxicity                 | 40 CFR 797.1400 (modified)                           | fathead minnow       | flow-through, 96 hr   | 0.6, 1.2, 2.5, 5, 10 mg/L (nominal)                | 20 (10/replicate) | The 96-hour LC <sub>50</sub> was 0.84 mg/L, and the NOEC (for both lethal and sublethal effects) was 0.51 mg/L.  | 55 FR 50055; 10/31/90<br>Fiche# OTS0530892 |
| Crotonaldehyde     | 4170-30-3 | EEATOX<br>Acute fish toxicity                 | 40 CFR 797.1400 (modified)                           | trout                | flow-through, 96 hr   | 0.12, 0.25, 0.5, 1, 2 mg/L (nominal)               | 20 (10/replicate) | The 96-hour LC <sub>50</sub> was 0.71 mg/L, and the NOEC (for both lethal and sublethal effects) was 0.25 mg/L.  | 55 FR 50055; 10/31/90<br>Fiche# OTS0530892 |
| Crotonaldehyde     | 4170-30-3 | EECLIF<br>Fish early life stage               | 40 CFR 797.1600 (modified)                           | fathead minnow       | flow-through  | 1.7, 0.87, 0.43, 0.22, 0.11, 0.054 mg/L (measured) | 40 eggs/dish      | The early life-stage experiment resulted in a LOEC of 0.22 mg/L, a NOEC of 0.11 mg/L and a MATC >0.11 mg/L and <0.22 mg/L.   | 58 FR 350; 1/5/93.<br>Docket# OPPTS-44594  |
| Crotonaldehyde     | 4170-30-3 | EECTOX<br>Chronic invertebrate toxicity       | 40 CFR 797.1330 (modified)                           | <i>Daphnia magna</i> | flow-through, 28 days   | 1.5, 0.76, 0.38, 0.19, 0.095 mg/L (nominal)        | 10/vessel         | The 28 day EC <sub>50</sub> value is >1.5 mg/L.  | 58 FR 350; 1/5/93,<br>Docket# OPPTS-44594  |
| Crotonaldehyde     | 4170-30-3 | EFADEG<br>Oxidation in water                  | Non-TSCA Protocol/Guideline (docket OPPTS #42108)    | Not applicable       | 25 °C, diluent water contained either 9 mg/L of dissolved oxygen (normal) or was purged with nitrogen | 6 mg/L   | Not applicable    | In normal diluent water, oxidation occurred rapidly, the test chemical concentration decreasing by almost 40% within 25 hours, and by almost 85% within 48 hours. In water purged with nitrogen, degradation occurred at about the same rate (presumed by the authors due to the small but significant amount of oxygen that purging did not remove).  | Fiche# OTS0530889                          |
| Crotonaldehyde     | 4170-30-3 | EFBDEG<br>Ready biodegradation: closed bottle | 40 CFR 796.3200 (modified)                           | Not applicable       | Closed bottle, 28 days, inoculum is secondary domestic wastewater                                     | 2.1 mg/L   | Not applicable    | No toxicity was seen at the concentration tested. The 28-day biodegradation was 55%, indicating crotonaldehyde is not readily biodegradable under these test conditions.   | 55 FR 50055; 10/31/90<br>Fiche# OTS0530892 |
| Dimethyl adipate   | 627-93-0  | HEGTOXCHRM<br>Micronucleus test               | National Toxicology Program (NTP)                    | Not specified        | Not specified   | Not specified                                      | Not specified     | Equivocal  | NTP Results Report 8/8/96                  |

## Results of Testing

| Chemical Name      | CAS No.   | Study Code/Type                      | Protocol/Guideline                                       | Species                       | Exposure   | Dose/Concentration  | No. per Group  | Results   | Reference                                 |
|--------------------|-----------|--------------------------------------|--|-------------------------------|--|---------------------|--|---|---|
| Dimethyl adipate   | 627-93-0  | HEGTOXMUTA<br>Ames test              | NTP  | <i>Salmonella typhimurium</i> | <i>in vitro</i>  | Not specified       | Not specified  | Negative response   | NTP Results Report 8/8/96                 |
| Dimethyl glutarate | 1119-40-0 | HEGTOXCHRM<br>Micronucleus test      | National Toxicology Program (NTP)                        | Not specified                 | Not specified  | Not specified       | Not specified  | Equivocal   | NTP Results Report 8/8/96                 |
| Dimethyl glutarate | 1119-40-0 | HEGTOXMUTA<br>Ames test              | NTP  | <i>Salmonella typhimurium</i> | <i>in vitro</i>  | Not specified       | Not specified  | Negative response   | NTP Results Report 8/8/96                 |
| Dimethyl succinate | 106-65-0  | HEGTOXMUTA<br>Ames test              | National Toxicology Program (NTP)                        | <i>Salmonella typhimurium</i> | <i>in vitro</i>  | Not specified       | Not specified  | Negative response   | NTP Results Report 8/8/96                 |
| Xylenes (mixed)    | 1330-20-7 | HECTOXCARC<br>Carcinogenicity        | National Toxicology Program (NTP)                        | F344/N rats                   | gavage, 1x/d., 5 d/wk, 103 weeks   | 0, 250, 500 mg/kg   | 50 male<br>50 female   | No evidence of carcinogenicity in male or female rats at either dose level. At no site was the incidence of nonneoplastic or neoplastic lesions in dosed rats of either sex considered to be related to administration of xylenes.  | NTP TR-327, Dec. 1986, NTIS PB87189684/AS |
| Xylenes (mixed)    | 1330-20-7 | HECTOXCARC<br>Carcinogenicity        | NTP  | B6C3F <sub>1</sub> mice       | gavage, 1x/d., 5 d/wk, 103 weeks   | 0, 500, 1000 mg/kg  | 50 male<br>50 female   | No evidence of carcinogenicity in male or female mice at either dose level. At no site was the incidence of nonneoplastic or neoplastic lesions in dosed mice of either sex considered to be related to administration of xylenes.  | NTP TR-327, Dec. 1986, NTIS PB87189684/AS |
| Xylenes (mixed)    | 1330-20-7 | HERTOXTERA<br>Developmental toxicity | Non-TSCA Protocol/<br>Guideline (see docket# OPTS-42025) | rats                          | inhalation, 6 hr/d during a 131-day pre-mating period and 20-day mating period, mated females continued during gestation days 1-20 and lactation days 5-20 | 0, 60, 250, 500 ppm | [1] 30 males, 60 females (0 ppm); [ 2, 3] 10 males, 20 females (60, 250 ppm); [4] 20 males , 40 females (500 ppm); [5] 10 males (500 ppm), 20 females (0 ppm); [6] 10 males (0 ppm), 20 females (500 ppm); | No mortality occurred in any of the treated groups. No adverse treatment-related effects were observed during the pre-mating period for F0 adults. In groups 3 and 6, mating indices were significantly lower than control. In group 4, F0 females, there was a statistically significant increase in mean kidney weight. Mean fetal weights (females only) for the high-dose group were lower than control. The incidence of fetuses in the high-dose group with at least one ossification variation was slightly higher than control. No other treatment-related effects were observed. | Docket# OPPTS-42025; study date 8/23/83   |
| Toluene            | 108-88-3  | HECTOXCARC<br>Carcinogenicity        | National Toxicology Program (NTP)                        | F344/N rats                   | inhalation, 6.5 hr/d, 5 d/wk, 2 years  | 0, 0.600, 1.200 ppm | 60 male<br>60 female   | No evidence of carcinogenicity in male or female rats at either dose level. Nephropathy was seen in almost all rats, and the severity was somewhat increased in exposed rats. Erosion of the olfactory epithelium and degeneration of the respiratory epithelium was increased in exposed rats. Inflammation of the nasal mucosa and metaplasia of the olfactory epithelium were increased in exposed female rats.  | NTP TR-371, Feb. 1990, NTIS PB90256371    |
| Toluene            | 108-88-3  | HECTOXCARC<br>Carcinogenicity        | NTP  | B6C3F <sub>1</sub> mice       | inhalation, 6.5 hr/d, 5 d/wk, 2 years  | 0, 0.600, 1.200 ppm | 60 male<br>60 female   | No evidence of carcinogenicity in male or female mice at either dose level. No biologically important increases were observed for any nonneoplastic or neoplastic lesions.  | NTP TR-371, Feb. 1990, NTIS PB90256371    |

## Results of Testing

| Chemical Name   | CAS No.       | Study Code/Type                                   | Protocol/Guideline  | Species      | Exposure   | Dose/Concentration                  | No. per Group | Results  | Reference  |
|---|---------------|---|---|--------------|--|-------------------------------------|---------------|--|--|
| Toluene   | 108-88-3      | HEEPID<br>Retrospective cohort<br>mortality study | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>42024) | humans       | Not reported   | Not reported                        | 7814          | A retrospective cohort mortality study conducted among white shoe manufacturing workers from 1940 to 1982 indicated that mortality due to leukemia and aleukemia was not statistically significantly elevated. Although, statistically significant excess mortality due to cancer of the trachea, bronchus and lung was observed in the total cohort (standardized mortality ratio (SMR) 147 (95% confidence interval 120-180) and a statistically significant trend in standardized relative risk with increasing potential latency, but not with increasing duration of employment. Chronic nonmalignant respiratory disease was significantly elevated among the men (SMR 158, 95% confidence interval 114-217), but was less than expected among women (SMR 79). | Walker, J.T., et al. Scand J Work Environ Health. 1993. 19:89-95.  |
| Toluene   | 108-88-3      | HERTOXTERA<br>Developmental<br>toxicity           | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>42024) | rats         | inhalation, 6 hr/d on<br>gestation days 6-15   | 0, 100, 400 ppm                     | Not reported  | There were no changes in the dams that indicated an adverse compound-related effect. There was no evidence of variation in fetal sex ratio, embryo toxicity, inhibition of fetal growth and development or teratogenic potential resulting from exposure of the dams to toluene.   | Docket# OPPTS-42024  |
| Toluene   | 108-88-3      | HESTOX<br>Subchronic Toxicity                     | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>42024) | mice         | oral, gavage, 5 d/wk<br>for 13 weeks   | 312, 625, 1250, 2500,<br>5000 mg/kg | 10/sex        | All animals receiving 5000 mg/kg died during the first week of the study. Over the 13 weeks of the study, 4 males and 4 females receiving 2500 mg/kg also died. Signs of toxicity seen in animals receiving 2500 and 5000 mg/kg included subconvulsive jerking, prostration, impaired grasping reflex, bradypnea, hypothermia, ataxia, and hypoactivity. No signs of treatment-related effects were detected in microscopic observations, organ weight means, or clinical pathology parameters. The maximum tolerated dose (MTD) observed was 1250 mg/kg.  | Fiche# OTS0533214,<br>Docket# OPPTS-42024  |
| Benzidine,<br><i>o</i> -toluidine,<br><i>o</i> -dianisidine | Not available | EFBDEG<br>Aerobic<br>biodegradation               | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>42001) | Not relevant | aerobic, conditions<br>similar to OECD<br>Ready Biodegrad-<br>ability Test 301A in<br>regard to inoculum<br>level and test medium. | 3 mg/l                              | Not relevant  | The chemicals studies, a selection of aromatic amines, possible biodegradation products of azo dyes, including <i>o</i> -dianisidine and 3,3'-dichlorobenzidine. Under the test conditions these products were not "readily biodegradable" but their "inherent biodegradability" was demonstrated. Results were confirmation using the OECD Inherent Biodegradability Test 302 B (Zahn-Wellens test).  | Fiche# OTS0507287,<br>ETAD (The<br>Ecological & Toxicol.<br>Assoc. of the<br>Dyestuffs Mfg.<br>Industry) Project E<br>3011 |
| Benzidine,<br><i>o</i> -toluidine,<br><i>o</i> -dianisidine | Not available | EFBDEG<br>Aerobic<br>biodegradation               | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>42001) | Not relevant | aerobic conditions, 28<br>days, sewage inoculum  | 20 mg/l DOC                         | Not relevant  | Results indicate the "readily biodegradable" of te 4 aromatic amines (aniline, p-anisidine, p-phenetidine and <i>o</i> -toluidine) and the "inherent biodegradability" of <i>o</i> -dianisidine and 3,3'-dichlorobenzidine. Therefore, if azo dyes are anaerobically cleaved to these amines, it is unlikely that they will remain unchanged in the environment.   | Brown, D., et al. The<br>aerobic biodegrad-<br>ability of primary<br>aromatic amines,<br>ETAD, Docket#<br>OPPTS-42002      |
| Benzidine,<br><i>o</i> -toluidine,<br><i>o</i> -dianisidine | Not available | EFBDEG<br>Anaerobic<br>biodegradation             | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>42001) | Not relevant | anaerobic conditions   | Not reported                        | Not relevant  | Under the test conditions a moderate rate of primary degradation was observed with Direct Red 7, Acid Red 114, and Direct Blue 15.   | Fiche# OTS0507287,<br>ETAD Project E 3010  |

## Results of Testing

| Chemical Name   | CAS No.       | Study Code/Type                       | Protocol/Guideline  | Species                         | Exposure                               | Dose/Concentration | No. per Group | Results   | Reference   |
|---|---------------|---------------------------------------|---|---------------------------------|--|--------------------|---------------|---|---|
| Benzidine,<br><i>o</i> -toluidine,<br><i>o</i> -dianisidine | Not available | EFBDEG<br>Anaerobic<br>biodegradation | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>42001) | Not relevant                    | 35 °C, anaerobic<br>conditions 42 days | Not reported       | Not relevant  | Studies were performed on 22 dyes chosen to be representative of major classes of dyestuffs and included Direct Red 7 as a positive control. The results show that with the single exception of Acid Blue 80 all the dyestuffs tested can show a substantial degree of colour removal and thus it seems that the breakdown of dyestuffs in the environment is likely to be initiated under anaerobic conditions.  | Brown, D., et al. The degradation of dyestuffs: Part 1: Primary biodegradation under anaerobic conditions, ETAD, Docket# OPPTS-42002        |
| Benzidine,<br><i>o</i> -toluidine,<br><i>o</i> -dianisidine | Not available | HEADME<br>Pharmacokinetics            | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>42001) | rats                            | Not reported                           | Not reported       | Not reported  | Experiments were performed on C-14-labeled Direct Blue 15 and Direct Red 2. The minimum detectable levels of both dyes in feces were 0.2 ppm. Based on radioassays, 74% of each dose was excreted via the feces; however, HPLC assays showed that only 11% of each dose was present as intact dye in the excrement.   | Fiche# OTS0507293, Levine, R.A., et al. 1982. J. Anal. Toxicol. 6: July/ August., FDA and National Center for Toxicological Research (NCTR) |
| Benzidine,<br><i>o</i> -toluidine,<br><i>o</i> -dianisidine | Not available | HEADME<br>Pharmacokinetics            | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>42001) | rats                            | oral (single dose)                     | 12 mg/kg           | Not reported  | The metabolism of Direct Blue 15 and Direct Red 2 in rats was studied. The base (DiMxBzd) of Direct Blue 15 was more extensively metabolized and most of the 14C in various extracts were identified as known metabolites. The base (DiMeBzd) of Direct Red 2 was more extensively metabolized with a small percentage of 14C identified as known metabolites. Distribution studies showed that liver, kidney, and lung accumulated and retained higher levels of 14C than other tissues (at 72 hrs). Peak levels of 14C, which occurred 8-12 hours after dosing were significantly higher with Direct Red 2 than Direct Blue 15. | Fiche# OTS0507294, Bowman, M.C., et al. 1982. J. Anal. Toxicol. 6: July/ August., NIOSH, FDA, and NCTR                                      |
| Benzidine,<br><i>o</i> -toluidine,<br><i>o</i> -dianisidine | Not available | HEADME<br>Pharmacokinetics            | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>42001) | rats                            | Not reported                           | 2 mg               | Not reported  | Peak levels of metabolites were excreted either 0-12 or 12-24 hr after the dyes were administered and, in seven of nine instances, no metabolites persisted in the urine after 48 hr. Minimum detectable levels of all metabolites were 12 ppb or less. All nine dyes were shown to be converted to measurable levels of their benzidine-congener-based metabolites in rats.  | Fiche# OTS0507292, NTP and NCTR   |
| Benzidine,<br><i>o</i> -toluidine,<br><i>o</i> -dianisidine | Not available | HEADME<br>Pharmacokinetics            | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>42001) | rats                            | Not reported                           | 2 mg               | Not reported  | Nine azo dyes based on dimethyl-, dimethoxy-, or dichloro-benzidine were studied to determine whether free amine congeners, their metabolites or conjugates were excreted in the urine. All 9 dyes were converted to measurable levels of their benzidine-congener-based metabolites. Peak levels of metabolites were excreted either 0-12 or 12-24 hr after the dyes were administered and, in seven of nine instances, no metabolites persisted in the urine after 48 hr. Minimum detectable levels of all metabolites were 12 ppb or less.   | Fiche# OTS0507292, National Toxicology Program (NTP) and NCTR   |
| Benzidine,<br><i>o</i> -toluidine,<br><i>o</i> -dianisidine | Not available | HECTOXTRFM<br>Cell transformation     | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>42001) | hamster (kidney<br>BHK21 cells) | <i>in vitro</i>                        | Not reported       | Not reported  | Direct Blue 14 and Direct Blue 53 produced positive results.  | Fiche# OTS0507287, ETAD Project T 2002  |

## Results of Testing

| Chemical Name   | CAS No.       | Study Code/Type  | Protocol/Guideline  | Species                                 | Exposure   | Dose/Concentration                                     | No. per Group | Results  | Reference  |
|---|---------------|--|---|---|--|--|---------------|--|--|
| Benzidine, <i>o</i> -toluidine, <i>o</i> -dianisidine | Not available | HEGTOXMUTA<br>Salmonella<br>microsome mutation<br>test | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>42001) | <i>Salmonella</i><br><i>typhimurium</i> | <i>in vitro</i> , with and<br>without S-9 activation | Not reported   | Not reported  | Direct Blue 14 produced negative results. Direct Blue 53 produced a positive result with activation.   | Fiche# OTS0507287,<br>ETAD Project T<br>2002,  |
| Benzidine, <i>o</i> -toluidine, <i>o</i> -dianisidine | Not available | HEGTOXMUTA<br>Salmonella<br>microsome mutation<br>test | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>42001) | <i>Salmonella</i><br><i>typhimurium</i> | <i>in vitro</i> , with and<br>without S-9 activation | 20, 100, 500, 2500, and<br>5000 µg/plate               | Not reported  | A dose-dependent mutagenic effect was observed for Acid Red 114 with the addition of S-9 mix with a maximal increase in the mutation rate by a factor of 4 from 250 µg to 1000 µg using TA 98 and from 500 µg to 1000 µg using TA 1538. A decrease in the number of colonies was observed from a dose greater than 1000 µg/plate. Inconclusive results were obtained using the tester strain TA 100.         | ETAD Project T<br>2015-3, Docket#<br>OPPTS-42002   |
| Benzidine, <i>o</i> -toluidine, <i>o</i> -dianisidine | Not available | HESTOX<br>Subacute toxicity                            | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>42001) | rats                                    | oral (gavage), 22 doses<br>over 30 days              | 1000 mg/kg b.w.  | Not reported  | All products, including Direct Blue 15, were tolerated without irreversible signs of toxicity and exhibited very low cumulative toxicity.  | ETAD Project T<br>2014, Fiche#<br>OTS0507287, Leist,<br>K.H.. Ecotox &<br>Environ Safety. 1982.<br>6: 457-463. |
| 2-Chlorotoluene                                       | 95-49-8       | EEATOX<br>Acute invertebrate<br>toxicity               | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-<br>42011)  | <i>Daphnia</i><br><i>magna</i>          | flow-through, 48 hr                                  | 0.33, 0.45, 0.72, 1.4, 4.5<br>mg/L                     | Not specified | The LC <sub>50</sub> value for 48 hours with the 95% confidence interval level were 1.1 mg/L and 1.0 - 1.2 mg/L, respectively. The no discernible effect concentration through 48 hours was 0.45 mg/L.   | 47 FR 54160; 12/1/82<br>Fiche# OTS0507447  |
| 2-Chlorotoluene                                       | 95-49-8       | EEATOX<br>Acute fish toxicity                          | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-<br>42011)  | Fathead<br>minnow                       | flow-through, 96 hr                                  | 0.35, 0.75, 1.0, 1.8, 3.8,<br>9.1 mg/L (measured)      | Not specified | The LC <sub>50</sub> value and its 95% confidence interval was calculated to be 7.5 mg/L and 6.1 to 9.8 mg/L, respectively. The no discernible effect concentration through 96 hours was 1.8 mg/L.   | 47 FR 54160; 12/1/82<br>Fiche# OTS0507449  |
| 2-Chlorotoluene                                       | 95-49-8       | EEATOX<br>Acute fish toxicity                          | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-<br>42011)  | Rainbow trout                           | flow-through, 96 hr                                  | 0, 0.56, 1.1, 2.2, 4.5,<br>9.0, 10.0 mg/L<br>(nominal) | Not specified | The 96-hour LC <sub>50</sub> and its 95% confidence interval for the test material was determined to be 2.3 mg/L and 1.8 to 3.0 mg/L, respectively. The no discernible effect concentration through 96 hours was determined to be 0.76 mg/L. This is the highest concentration tested at which there were no mortalities or observed behavioral and/or physical abnormalities.                               | 47 FR 54160; 12/1/82<br>Fiche# OTS0507448  |
| 2-Chlorotoluene                                       | 95-49-8       | EEBIOC<br>Metabolite<br>identification in fish         | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-<br>42011)  | Fathead<br>minnow                       | Not specified  | Not specified  | Not specified | Exposure to (C-14) 2-chlorotoluene were analyzed for C-14 metabolites. Analysis revealed that the majority of radiolabel belonged to the parent compound, 2-chlorotoluene (63-78% of the total C-14 in the fish). The remaining radioactivity was separated by reversed-phase liquid chromatography into four distinct zones containing C-14, none of which contributed over 10% of the total radioactivity. | 50 FR 5421; 2/06/85<br>Fiche# OTS0507461   |
| 2-Chlorotoluene                                       | 95-49-8       | EEBIOC<br>Fish bioconcentration                        | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-<br>42011)  | Fathead<br>minnow                       | flow-through, 22 d                                   | 0.100 mg/L (nominal)                                   | Not specified | Steady state was reached on day 7. Mean steady state BCF = 890 (± 340)X. Continuous elimination of C-14 residues was observed during the 14-d depuration period, with 87% eliminated by day 14.  | 49 FR 18779; 5/02/84<br>Fiche# OTS0507437  |

## Results of Testing

| Chemical Name   | CAS No. | Study Code/Type               | Protocol/Guideline   | Species              | Exposure  | Dose/Concentration                     | No. per Group                | Results  | Reference                                     |
|-----------------|---------|-------------------------------|--|----------------------|---|--|------------------------------|--|---|
| 2-Chlorotoluene | 95-49-8 | EECLIF<br>Embryo-larval test  | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42011) | Fathead minnows      | flow-through, 30 d  | 6 levels ranging from 0.25 to 7.1 mg/L | Not specified                | Survival of larvae exposed to mean measured concentrations of 2.9 and 7.1 mg/L was significantly reduced when compared to controls. No adverse effects on embryo hatchability or survival and growth of larvae were noted. The maximum acceptable concentration of test material for embryos and larvae was estimated to be >1.4 and <2.9 mg/L.  | 47 FR 54160; 12/1/82<br>Fiche# OTS0507450     |
| 2-Chlorotoluene | 95-49-8 | EECTOX<br>Chronic study       | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42011) | <i>Daphnia magna</i> | flow-through, 21 d  | 0.014-0.73 mg/L                        | Not specified                | All test animals exposed to the highest test concentration died within the first 8 days of the exposure period. Test animal survival in the next two highest test concentrations (0.16 and 0.21 mg/L) were significantly reduced as compared to the survival of the control group. The estimated maximum acceptable toxicant concentration (MATC) after 21 days of exposure was >0.21 and <0.73 mg/L.  | 51 FR 39799;<br>10/31/86<br>Fiche# OTS0510662 |
| 2-Chlorotoluene | 95-49-8 | EFTSPT<br>Dissipation in soil | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42011) | Not applicable       | C-14 labeled emul-sifiable concentrate was applied as a surface spray, then incorporated into top 3 in. of soil 30 minutes after application. Two plots were treated at 1 lb/A and 2 at 2 lbs/A. Soybeans and tomatoes were planted 4 hr after treatment. | Not specified                          | Not applicable               | Less than 1% test material remained on the soil 24 hours after application. Plants grown in treated soil contained no radioactive residues when analyzed 43 days after planting.   | Fiche# OTS0507450                             |
| 2-Chlorotoluene | 95-49-8 | HEADME<br>Metabolism study    | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42011) | rats                 | intravenous, single dose  | 0.7 mg/kg                              | unreported number of females | A single dose of [U-ring- <sup>14</sup> C] test material was administered to test animals. The test animals eliminated 18 to 69% and 14 to 18% of the label in the urine and expired volatile, respectively. The test material was rapidly eliminated by the test animals within 4 days after exposure.  | 49 FR5187; 2/10/84<br>Fiche# OTS0507459       |
| 2-Chlorotoluene | 95-49-8 | HEADME<br>Metabolism study    | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42011) | rats                 | gavage, single dose   | 320 mg/kg                              | 3 males                      | The excretion of radioactive unchanged test material in expired air totaled 11.3% after 24 hours (6.1% during 0-3 hours, 3.7% during 3-6 hours, and 1.5% during 6-24 hours). The excretion of radioactivity in the urine and feces were 81.7 and 3.5% respectively. No unchanged test material was detected in the urine, and no radioactivity was extracted from the urine by cyclohexane. Metabolites of <sup>14</sup> C-test material were chloro-methyl-o-phenylmercapturic acid (22%), 2-chloro alcohol gluconuride (41%), 2-chlorohippuric acid (19%), 2-chlorobenzyl alcohol (1%), 2-chlorobenzoic acid (1%), 2-chlorobenzoic acid gluconuride (1%), and unidentified polar metabolites (1%). | 48 FR 34119; 7/27/83<br>Fiche# OTS0507354     |
| 2-Chlorotoluene | 95-49-8 | HEADME<br>Metabolism study    | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42011) | rats                 | gavage, single dose   | 1.0 mg/kg                              | 4 male;<br>4 female          | No significant sex-related metabolism differences were found between the males and females. Of the administered <sup>14</sup> C, 85 to 92%, 5 to 8%, and 1 to 4% were excreted in the urine, feces, and as volatile <sup>14</sup> C, respectively.   | 48 FR 20132; 5/4/83<br>Fiche# OTS0507452      |

## Results of Testing

| Chemical Name   | CAS No. | Study Code/Type                             | Protocol/Guideline   | Species                       | Exposure   | Dose/Concentration                       | No. per Group                | Results   | Reference                                 |
|-----------------|---------|---|--|-------------------------------|--|--|------------------------------|---|---|
| 2-Chlorotoluene | 95-49-8 | HEADME<br>Diuretic study                    | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42011) | rats                          | oral (dietary), 4 d  | 0, 30, 100, 300, 1000 mg/kg/d            | unreported number of females | At the 1000 mg/kg/day dose, the test material caused an increase in urine output at 6 and 24 hours after dosing for day 3. Urinalysis showed a statistically significant increase in calcium ion excretion at the 300 mg/kg/day dose level, and inorganic phosphorous excretion at the 1000 mg/kg/day dose level. | 50 FR 31919; 8/7/85<br>Fiche# OTS0507462  |
| 2-Chlorotoluene | 95-49-8 | HEATOX<br>Acute dermal toxicity             | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42011) | rabbits                       | dermal, clipped skin was abraded in 3/intact in 3, 1 d                           | 2165 mg/kg                               | Not specified                | Undiluted compound led to no signs of systemic toxicity. The LD <sub>50</sub> was >2165 mg/kg after a 14-day observation period.  | Fiche# OTS0507354                         |
| 2-Chlorotoluene | 95-49-8 | HEATOX<br>Acute inhalation toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42011) | rats                          | inhalation (head only), 1 hr   | 63 mg/L vapor                            | 10/sex                       | No mortalities occurred. The LC <sub>50</sub> is >63 mg/L.  | Fiche# OTS0507354                         |
| 2-Chlorotoluene | 95-49-8 | HEATOX<br>Acute rat and mouse oral toxicity | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42011) | rats and mice                 | oral, single dose  | 2165-3951 (rat); 2250-5000 mg/kg (mouse) | 10/sex                       | In rats, undiluted 2-chlorotoluene caused some mortality at all levels The LD <sub>50</sub> values were 3031 mg/kg for females and 3464 mg/kg for males. In mice, 20% emulsion in 5% alcohol led to LD <sub>50</sub> values of 3902 mg/kg for females and 3776 mg/kg for males.                                   | Fiche# OTS0507354                         |
| 2-Chlorotoluene | 95-49-8 | HEDIRR<br>Primary dermal irritation         | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42011) | rabbits                       | dermal, clipped skin was abraded in 3/intact in 3, 1 d                           | 2165 mg/kg                               | Not specified                | Undiluted compound led to slight edema and erythema at application sites that healed during the 13-day observation period.  | Fiche# OTS0507354                         |
| 2-Chlorotoluene | 95-49-8 | HEDSEN<br>Dermal sensitization              | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42011) | guinea pigs                   | dermal, 3x/wk for 3 wks followed by 10-d rest period and a challenge application | 10 or 25% as acacia emulsion             | 10 females                   | Slight erythema and occasional edema, but no indication of contact sensitization were noted with the 10% emulsion. The 25% emulsion caused severe dermal irritation, but no indication of sensitization. Two high-exposure animals died, possibly from bacterial or viral infections entering at irritation sites | Fiche# OTS0507354                         |
| 2-Chlorotoluene | 95-49-8 | HEEIRR<br>Primary eye irritation            | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42011) | rabbits                       | eye/animal without rinsing, observed at 1, 2, 3, and 7 hr, 1 d                   | neat                                     | 3/sex                        | Undiluted compound led to slight conjunctival inflammation that cleared by day 7. No inflammation of the iris was seen. Staining with sodium fluorescent at 24 hours showed 10% corneal surface staining in 1 rabbit.   | Fiche# OTS0507354                         |
| 2-Chlorotoluene | 95-49-8 | HEGTOXCHRM<br>Cytogenetic                   | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42011) | Chinese hamster ovaries (CHO) | <i>in vitro</i>  | 0.83-250.0 nL/mL                         | Not applicable               | There were no significant increases in chromosomal damage in the cultures tested up to the toxic dose (83.3 nL/mL in the absence of metabolic activation). In the presence of metabolic activation, there were no increases in aberrations in the test cultures up to 83.3 nL/mL.                                 | 47 FR 54160; 12/1/82<br>Fiche# OTS0507446 |
| 2-Chlorotoluene | 95-49-8 | HEGTOXCHRM<br>Chromosomal aberration assay  | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42011) | rats                          | gavage, 1x/dy; 5 d,  | 30, 100, 300 mg/kg                       | 4 male;<br>4 female          | The frequencies of structural aberrations in bone marrow cells of treated test animals did not significantly differ from the negative controls at any of the dose levels for either sex.  | 47 FR 54160; 12/1/82<br>Fiche# OTS0507445 |
| 2-Chlorotoluene | 95-49-8 | HEGTOXMUTA<br>Mutation assay                | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42011) | mouse (L5178YTK +/- cells)    | <i>in vitro</i>  | 40-90 nL/mL                              | Not applicable               | The test material produced a relative growth of 6.1 to 69.7%. None of the activated cultures produced frequencies of mutations significantly greater than the solvent control Dimethylsulfoxide (DMSO).   | 51 FR 6468; 2/24/86<br>Fiche# OTS0509042  |



## Results of Testing

| Chemical Name   | CAS No. | Study Code/Type                      | Protocol/Guideline   | Species                       | Exposure                                     | Dose/Concentration                 | No. per Group         | Results   | Reference                                 |
|-----------------|---------|--------------------------------------|--|-------------------------------|--|------------------------------------|-----------------------|---|---|
| 2-Chlorotoluene | 95-49-8 | HEGTOXMUTA<br>Mutagenicity study     | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42011) | <i>Salmonella typhimurium</i> | <i>in vitro</i>                              | 0.02-1.17 µL/plate                 | Not applicable        | The test strains used were TA98, TA100, TA1535, and TA1538. The test material diluted with DMSO did not cause a reproducible positive response in any of the bacterial tester strains, either with or without metabolic activation.   | 47 FR 36958; 8/24/82<br>Fiche# OTS0507442 |
| 2-Chlorotoluene | 95-49-8 | HEGTOXMUTA<br>Mutagenicity study     | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42011) | mouse<br>(L5178TK +/- cells)  | <i>in vitro</i>                              | 40-60 nL/mL                        | Not applicable        | Percent relative growth ranged from 19.3% to 58.3% in the absence of activation and 23.8% to 127.8% with activation. The test material did not produce significant increases in mutant frequencies.   | 47 FR 54160; 12/1/82<br>Fiche# OTS0507444 |
| 2-Chlorotoluene | 95-49-8 | HEGTOXTRFM<br>Transformation assay   | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42011) | mouse<br>(Balb/3T3)           | <i>in vitro</i>                              | 138.0-1375.0 nL/mL                 | Not applicable        | Relative cell survivals ranged from 100% to 20%. No evidence of dose-related responses were observed at any concentration, with or without metabolic activation.  | 47 FR 54160; 12/1/82<br>Fiche# OTS0507430 |
| 2-Chlorotoluene | 95-49-8 | HERTOXTERA<br>Developmental toxicity | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42011) | rats                          | inhalation, 6 hr/d;<br>6-19 of gestation     | 0, 1.0, 3.0, 9.0 mg/L<br>(nominal) | 100 females           | At 9 mg/L, all parent animals showed brown fur staining, slight to moderate ataxia, and some lacrimation and/or salivation during exposure. Food consumption and mean weight gain were significantly reduced at 9 mg/L. At 9 mg/L, values for litters and mean fetal weight were significantly reduced. There were no significant effects upon litter size, and pre- and post implantation loss. Also, at the high dose, skeletal ossification was reduced, providing an increased incidence of fetuses with sternal variants, and contributing to a significant increase in fetuses with skeletal abnormalities. | 48 FR 20132; 5/4/83<br>Fiche# OTS0507458  |
| 2-Chlorotoluene | 95-49-8 | HERTOXTERA<br>Developmental toxicity | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42011) | rabbits                       | inhalation, 6 hr/d<br>inclusive of gestation | 0, 1.5, 4, 10 mg/L<br>(nominal)    | 16 females            | At the nominal concentration of 10 mg/L, observations included lacrimation, salivation, and ptosis. At concentrations 4 and 10 mg/L, there were significant dose-related reductions in food consumption during the treatment period, which resulted in retardation of mean weight gain between the onset of treatment and day 9 of gestation. There were no significant effects upon mean values for litter size, pre- and post implantation loss, or litter and mean fetal weight. There were no effect upon the incidence of skeletal anomalies and variants.   | 48 FR 20132; 5/4/83<br>Fiche# OTS0507457  |
| 2-Chlorotoluene | 95-49-8 | HESTOX<br>Subchronic study           | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42011) | rabbits                       | inhalation, 6hr/d;<br>14 d                   | 4, 8, 12, 16 mg/L                  | Not specified         | A summary of results is presented. Observations included decreased respiration at 4 mg/L, and at higher exposures, salivation, lacrimation, slight CNS (central nervous system) depression, increased water consumption, and decreased body weight gain. A NOAEL was not identified.  | 48 FR 34119; 7/27/83<br>Fiche# OTS0507456 |
| 2-Chlorotoluene | 95-49-8 | HESTOX<br>Subchronic study           | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42011) | rats                          | oral (gavage), 90 d                          | 0, 100, 300, 1000<br>mg/kg/d       | 15 male;<br>15 female | There were no chemical related mortalities observed at any dose level. A slight decrease in body weight gain (300 and 1,000 mg/kg/day), salivation, and excessive urination (1,000 mg/kg/day) were observed.  | 48 FR 34119; 7/27/83<br>Fiche# OTS0507456 |

## Results of Testing

| Chemical Name             | CAS No.  | Study Code/Type                             | Protocol/Guideline                                   | Species                                     | Exposure  | Dose/Concentration                | No. per Group        | Results   | Reference                                   |
|---------------------------|----------|---|--|---|---|-----------------------------------|----------------------|---|---|
| 1,2-Butylene Oxide        | 106-88-7 | HECTOXCARC Carcinogenicity                  | National Toxicology Program (NTP)                    | rats  | inhalation, 6 hr/d, 5 d/wk, 103 weeks   | 0, 200, 400 ppm                   | 50 male<br>50 female | Clear evidence of carcinogenicity in male rats as shown by an increased incidence of papillary adenomas of the nasal cavity, alveolar/bronchiolar carcinomas, and alveolar/bronchiolar adenomas or carcinomas (combined). Equivocal evidence of carcinogenicity in female rats as shown by the presence of papillary adenomas of the nasal cavity. Exposure was associated with adenomatous hyperplasia and inflammatory lesions of the nasal cavity.   | NTP TR-329, March 1988, NTIS PB88-216262/AS |
| 1,2-Butylene Oxide        | 106-88-7 | HECTOXCARC Carcinogenicity                  | NTP  | mice  | inhalation, 6 hr/d, 5 d/wk, 103 weeks   | 0, 50, 100 ppm                    | 50 male<br>50 female | No evidence of carcinogenicity in male or female mice at either dose level. Exposure was associated with inflammatory lesions of the nasal cavity.  | NTP TR-329, March 1988, NTIS PB88-216262/AS |
| 1,2-Butylene Oxide        | 106-88-7 | HEDSEN Sensitization study (Voluntary test) | Non-TSCA Protocol/Guideline (see docket #OPTS-42049) | guinea pigs                                 | dermal, 4x at 48 hr intervals; challenged 14 d later  | Not specified                     | 10 (males)           | Following a 2 week rest period, test animals received a challenge dose of an unspecified amount of test material. Observations revealed that there was no sensitization reaction in any of the test animals when compared to controls.  | 49 FR 18779; 5/2/84<br>Fiche# OTS0507304    |
| 4-Chlorobenzo-trifluoride | 98-56-6  | EEBIOC Bioconcentration                     | Non-TSCA Protocol/Guideline (see docket #OPTS-42026) | Bluegill sunfish                            | 96 hr, flow-through   | 0.025, 0.250 ppm (nominal)        | Not specified        | Bioconcentration values were determined to be 121.8 to 202.0. This demonstrates that the test material has a low to moderate potential for bioaccumulation in fish. The rapid and extensive elimination of the radioactive residues indicates that the test compound-related residues would not persist in fish tissue after removal from exposure.   | 48 FR 53159; 11/25/83<br>Fiche# OTS0507307  |
| 4-Chlorobenzo-trifluoride | 98-56-6  | EECLIF Fish early life stage                | Non-TSCA Protocol/Guideline (see docket #OPTS-42026) | <i>Pimephales promelas</i> (fathead minnow) | 31 days   | 0.070, 0.12, 0.26, 0.54, 1.4 mg/L | Not specified        | Exposure to concentrations as high as 1.4 mg/l had no effect on percentage hatch of embryos. However, percentage survival of larvae to 1.4 mg/L was significantly reduced. Exposure to concentrations less than 1.4 mg/L had no effect on larvae survival. Mean total length and average wet weight of larvae was unaffected.   | 48 FR 32730<br>Fiche# OTS0508145            |
| 4-Chlorobenzo-trifluoride | 98-56-6  | EECTOX Daphnid chronic toxicity             | Non-TSCA Protocol/Guideline (see docket #OPTS-42026) | <i>Daphnia magna</i>                        | 21 d, flow-through  | 0.01, 0.03, 0.05, 0.14, 0.20 mg/L | Not specified        | The LC <sub>50</sub> values for 4, 7, 14, and 21 days, respectively, were 0.163, 0.150, 0.073, and 0.071 mg/L. The no-effect level was 0.03 mg/L. Decreased reproduction was noted at 0.05 mg/L.  | Fiche# OTS0508142                           |
| 4-Chlorobenzo-trifluoride | 98-56-6  | EFADEG Atmospheric fate                     | Non-TSCA Protocol/Guideline (see docket #OPTS-42026) | Not applicable                              | 75-, and 175-liter 2-chambered teflon bag, ultrazero or zero air with added NO <sub>2</sub> , blacklight irradiation. | Not applicable                    | Not applicable       | The rate constants determined were: k(OH) = (2.3 ± 0.8) × 10 <sup>-13</sup> cm <sup>3</sup> molecule <sup>-1</sup> sec <sup>-1</sup> ; k(photolysis) = <2.7 × 10 <sup>-6</sup> sec <sup>-1</sup> , and k(O <sub>3</sub> ) = <5 × 10 <sup>-21</sup> cm <sup>3</sup> molecule <sup>-1</sup> sec <sup>-1</sup> . Estimated atmospheric lifetimes due to these reactions were ~50 days for the reaction with OH radicals, >6.5 days for photolysis, and >8.8 years for the reaction with O <sub>3</sub> . | 50 FR 5421; 2/6/85<br>Fiche# OTS0508169     |
| 4-Chlorobenzo-trifluoride | 98-56-6  | EFADEGPHOT Photolysis in water              | Non-TSCA Protocol/Guideline (see docket #OPTS-42026) | Not applicable                              | 28 d, sterile water, sunlight   | 10 µg/mL                          | Not applicable       | The results indicate that the test material did not dissipate during the 28 day study.  | 48 FR 53159; 11/25/83<br>Fiche# OTS0507306  |

## Results of Testing

| Chemical Name             | CAS No. | Study Code/Type                                    | Protocol/Guideline  | Species        | Exposure  | Dose/Concentration                                      | No. per Group       | Results   | Reference                                |
|---------------------------|---------|--|---|----------------|---|---|---------------------|---|--|
| 4-Chlorobenzo-trifluoride | 98-56-6 | EFBDEG<br>Aerobic biodegrada-<br>tion              | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42026) | Not applicable | 11 d, soil and sewage                                 | 4, 8, 10 mg carbon/L                                    | Not applicable      | Based on the data obtained, no conclusions could be drawn concerning biodegradation of the test material. The highly volatile nature of the test material caused significant losses of radioactivity from the cultures. Only 13% of the initial theoretical radioactivity could be accounted for in day 0 samples. By the 5th day, less than 2% remained. The study, which was scheduled to last for 28 days, was terminated on the 11th day.   | 49 FR 18779; 5/2/84<br>Fiche# OTS0507306 |
| 4-Chlorobenzo-trifluoride | 98-56-6 | EFBDEG<br>Anaerobic biodegrada-<br>tion            | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42026) | Not applicable | 59 d, anaerobic<br>digester sludge                    | 8 µL/vial, equivalent to<br>50 mg carbon/L of<br>medium | Not applicable      | Samples were extracted and quantified using gas chromatography-mass spectrometer. The gas evolution data indicated that all of the ethanol and 64% of the test material was biodegraded during the 59-day test. The test material had a slight inhibitory effect on gas production during the first 17 days, but this condition disappeared during the next 7 days. A total of 96% of the added test material was accounted for either as evolved gas or residual test material in the sludge-containing test vials. Only 23% could be accounted for in the sludge-free controls. It was theorized that 77% was lost through either leakage, adsorption to the stopper, or through non-biological degradation. Due to the volatility of the test material, it is theorized that it would not accumulate in any natural anaerobic environment. | 49 FR 18779; 5/2/84<br>Fiche# OTS0507306 |
| 4-Chlorobenzo-trifluoride | 98-56-6 | EFTSPT<br>Soil and sediment<br>adsorption isotherm | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42026) | Not applicable | 4 hr, clay and sandy<br>loams, 2 aquatic<br>sediments | 0.0847, 0.221, 0.530,<br>2.45, 4.07, 9.92 µL/mL         | Not applicable      | Six different concentrations of <sup>14</sup> C labeled test material were equilibrated with 5 gram portions of soil or sediment. Adsorption coefficients (K <sub>a</sub> ) ranged from 3.65 for the sandy loam soil to 9.10 for the clay loam soil. The corresponding adsorption coefficients based upon soil organic carbon (K <sub>oc</sub> ) ranged from 420 to 530.  | 49 FR 18779; 5/2/84<br>Fiche# OTS0507306 |
| 4-Chlorobenzo-trifluoride | 98-56-6 | EFTSPTVOLZ<br>Volatilization from<br>water         | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42026) | Not applicable | water   | 10 mg/L   | Not applicable      | In the experiment, 1800 mL of water was purged with nitrogen (to remove dissolve oxygen), and then fortified with the test material to a final concentration of 10 mg/L. The ratio of volatilization rate to the oxygen reaeration rate (K <sub>PCHT</sub> /K <sub>OD</sub> ) was determined to be 0.64 ± 0.04. This result shows that the volatilization rate from natural waters was slightly slower than the oxygen reaeration rate.   | 49 FR 18779; 5/2/84<br>Fiche# OTS0507306 |
| 4-Chlorobenzo-trifluoride | 98-56-6 | HEADME<br>Metabolism study                         | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42026) | rat            | gavage, single dose                                   | 1.0 mg/kg   | 3 male;<br>5 female | Of the administered label, 3 to 4% was excreted in the feces and 14 to 15% was excreted in the urine over the 4 day test period. 62 to 82% of the dose was rapidly expired unchanged by the test animals (the time period for expiration was not reported). The test material was excreted unchanged as the major fecal constituent. Levels of labelled residues in the tissues were low; 4 days after dosing, 1% of the applied label remained and was located in fat tissue.  | 48 FR 20132; 5/4/83<br>Fiche# OTS0507284 |
| 4-Chlorobenzo-trifluoride | 98-56-6 | HEATOX<br>Acute oral toxicity                      | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42026) | rat            | oral (gavage), single<br>dose                         | 5 ml/kg body weight                                     | 8/sex               | Mortality in two males. LD <sub>50</sub> is estimated to be >5 ml/kg. Clinical signs included hypoactivity, tremors, ataxia, decreased limb tone, piloerection, and blood on nose. Lesions were seen in the thymus, lungs and in the uterus of one female.  | Fiche# OTS0508138                        |

## Results of Testing

| Chemical Name             | CAS No.  | Study Code/Type                                     | Protocol/Guideline                                       | Species                           | Exposure   | Dose/Concentration               | No. per Group         | Results   | Reference                                     |
|---------------------------|----------|---|--|-----------------------------------|--|----------------------------------|-----------------------|---|---|
| 4-Chlorobenzo-trifluoride | 98-56-6  | HECTOXTRFM<br>Morphological transformation          | Non-TSCA Protocol/<br>Guideline (see docket #OPTS-42026) | mouse                             | <i>in vitro</i>  | 0, 10, 30, 100, 300, µg/mL       | Not applicable        | There was no significant increase in the appearance of transformed foci in Balb/C-3T3 cells over the concentration range tested, with or without S9 activation. Toxicity to cells was apparent at 300 µg/mL. At this level, the compound was not completely soluble.  | 49 FR 18779; 5/2/84<br>Fiche# OTS0507306      |
| 4-Chlorobenzo-trifluoride | 98-56-6  | HEGTOXCHRM<br>Mammalian chromosomal aberration test | Non-TSCA Protocol/<br>Guideline (see docket #OPTS-42026) | rats                              | single dose, gavage  | 0, 0.5, 1.7, 5.0 mL/kg           | 5 male;<br>5 female   | Results showed that the test material did not induce chromosomal aberrations in male or female test animals. Clinical signs of toxicity included excess lacrimation and salivation in the male and female animals receiving 5 mL/kg. Male and female animals receiving 5 and 1.7 mL/kg appeared lethargic. No mortalities were observed at 5.0 mg/kg or less.   | 48 FR 20132; 5/4/83<br>Fiche# OTS0507306      |
| 4-Chlorobenzo-trifluoride | 98-56-6  | HERTOXTERE<br>Reproductive/fertility effects        | Non-TSCA Protocol/<br>Guideline (see docket #OPTS-42026) | rat                               | oral (gavage). 4 wks prior to mating continuously through one reproduction period until F1 litters were weaned; selected F1 rats were exposed for 90 days, then sacrificed | 0, 5, 15, 45 mg/kg/day           | Not specified         | Mid- and high-dose F <sub>0</sub> rats showed decreased weight and weight gain. F <sub>1</sub> female rats had decreased weight gain and monocytes, increased serum glutamic-pyruvic transaminase, decreased red blood cell counts, and mean corpuscular hemoglobin (both sexes), and lung lesions.   | Fiche# OTS0508148                             |
| 4-Chlorobenzo-trifluoride | 98-56-6  | HESTOX<br>Subchronic oral toxicity                  | Non-TSCA Protocol/<br>Guideline (see docket #OPTS-42026) | rat                               | gavage, 1x/d; 90 d   | 0, 10, 40, 150, 500 mg/kg/d      | 15 male;<br>15 female | No physical signs of toxicity were observed in males or females during treatment. Observations included an initial decrease in mean body weight gain, decreased mean food consumption, decreased efficiency of food utilization, and mild proteinuria in males at 500 mg/kg and in females at 150 and 500 mg/kg. Increased liver weights at all doses in males, and at the three highest doses in females. Significant effects observed only in male test animals were decreased erythrocytes, hemoglobin, and mean corpuscular volume at 500 mg/kg, and packed cell volume at 150 and 500 mg/kg. | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0507306 |
| <i>p</i> - Cresol         | 106-44-5 | HECTOXTRFM<br>Morphological transformation study    | 40 CFR 795.285 (modified)                                | mice, BALB/C-3T3 cells            | <i>in vitro</i>  | 0.81-15.0 nL/mL                  | Not applicable        | <i>p</i> -Cresol produced a dose-related increase in the number of foci/plate over the entire concentration range. The test material induced cell transformation that was significantly elevated when compared to the controls.   | 53 FR 27564; 7/21/88<br>Fiche# OTS0517694     |
| <i>p</i> - Cresol         | 106-44-5 | HEGTOXCHRM<br>Mammalian cytogenicity study          | 40 CFR 798.5375 (modified)                               | Chinese hamster ovary cells (CHO) | <i>in vitro</i>  | 10, 50, 250, 500, 749, 999 µg/mL | Not applicable        | The test materials did not induce chromosomal aberrations either in the presence or absence of metabolic activation.  | 53 FR 27564; 7/21/88<br>Fiche# OTS0517691     |
| <i>p</i> - Cresol         | 106-44-5 | HEGTOXCHRM<br>Rodent dominant lethal assay          | 40 CFR 798.5450 (modified)                               | mice                              | gavage   | 0, 100, 275, 550 mg/kg bw        | 25/group              | The treatment had no adverse effects with respect to number of early and late resorptions, and live implants, indicating that the test compound did not induce dominant lethal mutations in male germ cells of mice under the conditions of this assay.   | 54 FR 30460; 7/20/89<br>Fiche# OTS0529223     |
| <i>p</i> - Cresol         | 106-44-5 | HEGTOXMUTA<br>Sex-linked recessive lethal assay     | 40 CFR 798.5275 (modified)                               | <i>Drosophila melanogaster</i>    | oral (dietary), 3 d  | 0, 60, 300, 600 µg/mL            | 200-300/group         | The treatment did not increase the frequency of sex-linked recessive lethal mutations, indicating that the test substance was not mutagenic in <i>Drosophila</i> under the conditions of this assay.  | 54 FR 14861; 4/13/89<br>Fiche# OTS0529221     |

## Results of Testing

| Chemical Name     | CAS No.  | Study Code/Type  | Protocol/Guideline            | Species                                 | Exposure                                  | Dose/Concentration  | No. per Group                   | Results   | Reference                                     |
|-------------------|----------|--|-------------------------------|---|---|---|---------------------------------|---|---|
| <i>p</i> - Cresol | 106-44-5 | HEGTOXMUTA<br>Mutagenicity study                             | 40 CFR 798.5375<br>(modified) | mouse L5178Y<br>TK +/-                  | <i>in vitro</i>                           | 6.39-818 µg/mL<br>(nonactivated)<br>0.128-40.9 µg/mL<br>(activated) | Not applicable                  | None of the treatments caused increased mutant frequencies greater than 2-fold over the solvent control mutant frequency. The test materials were considered to have no genotoxic effects and were nonmutagenic either in the presence or absence of metabolic activation.  | 53 FR 27564; 7/21/88<br>Fiche# OTS0517693     |
| <i>p</i> - Cresol | 106-44-5 | HERTOXTERA<br>Developmental<br>toxicity                      | 40 CFR 798.4900               | rabbits                                 | oral (gavage), days 6-<br>18 of gestation | 0, 5.0, 50.0, 100.0<br>mg/kg/d                                      | 14 pregnant<br>females          | There were no treatment-related deaths, abortions, or early deliveries. Clinical signs of toxicity (audible respiration and ocular discharge) were observed at 50 and 100 mg/kg/day. At 50 and 100 mg/kg/day hypoactivity was observed. For <i>p</i> -cresol only, observations included gasping, cyanosis, and audible labored and rapid respiration. There were no treatment-related effects on food consumption or incidence of any malformations. | 53 FR 27564; 7/21/88<br>Fiche# OTS0517695     |
| <i>p</i> - Cresol | 106-44-5 | HERTOXTERA<br>Developmental<br>toxicity                      | 40 CFR 798.4900               | rats                                    | oral (gavage), days 6-<br>15 of gestation | 0, 30.0, 175.0,<br>450.0 mg/kg/d                                    | 25 pregnant<br>females          | At 450 mg/kg/day, there was a significant reduction in maternal body weight gain during the dosing period. At 450 mg/kg/day, clinical signs of toxicity were hypoactivity, ataxia, tremors, twitches, prone positioning, audible respiration, and peroral wetness. Fetal body weights per litter were reduced at 450 mg/kg/day. There were no significant changes in the incidence of any individual malformations for any dose group.                | 53 FR 27564; 7/21/88<br>Fiche# OTS0517695     |
| <i>p</i> - Cresol | 106-44-5 | HERTOXTERE<br>2-Generation<br>reproduction study             | 40 CFR 798.4900<br>(modified) | rats                                    | gavage                                    | 0, 30, 175, 450 mg/kg<br>bw/day                                     | 25/sex/<br>generation/<br>group | No treatment related reproductive effects were observed in this 2-generation gavage study. The NOEL's for parental animals and offspring were 30 and 175 mg/kg bw/day, respectively.  | 54 FR 52449;<br>12/21/89 Fiche#<br>OTS0529224 |
| <i>m</i> - Cresol | 108-39-4 | HECTOXTRFM<br>Morphological<br>transformation study          | 40 CFR 795.285<br>(modified)  | mice,<br>BALB/C-3T3<br>cells            | <i>in vitro</i>                           | 6.0-72.0 nL/mL  | Not applicable                  | <i>m</i> -Cresol was evaluated for its ability to induce cell transformation. Results indicated that the test material did not produce significant increases in the number of transformed loci, with or without activation.   | 53 FR 51134;<br>12/20/88<br>Fiche# OTS0517698 |
| <i>m</i> - Cresol | 108-39-4 | HECTOXTRFM<br>Morphological<br>transformation study          | 40 CFR 795.285<br>(modified)  | mice, BALB/C-<br>3T3 cells              | <i>in vitro</i>                           | 0.57-48.0 nL/mL   | Not applicable                  | Results indicated that the test material did not induce cell transformation, with or without activation.  | 53 FR 27564; 7/21/88<br>Fiche# OTS0517694     |
| <i>m</i> -Cresol  | 108-39-4 | HEGTOXCHRM<br>Mammalian<br>cytogenicity study                | 40 CFR 798.5375<br>(modified) | Chinese<br>hamster ovary<br>cells (CHO) | <i>in vitro</i>                           | 10, 50, 250, 500, 749,<br>999 µg/mL                                 | Not applicable                  | The test materials did not induce chromosomal aberrations either in the presence or absence of metabolic activation.  | 53 FR 27564; 7/21/88<br>Fiche# OTS0517691     |
| <i>m</i> - Cresol | 108-39-4 | HEGTOXCHRM<br>Mammalian bone<br>marrow cytogenicity<br>study | 40 CFR 798.5385<br>(modified) | mice                                    | gavage                                    | 0, 96, 329, 960 mg/kg   | 5/sex/group                     | The treatment did not increase the frequency of chromosomal aberrations, indicating that <i>m</i> -cresol was not clastogenic in mice under the conditions of this assay.   | 54 FR 7093; 2/16/89<br>Fiche# OTS0529219      |
| <i>m</i> - Cresol | 108-39-4 | HEGTOXDNAF<br>Unscheduled DNA<br>synthesis                   | 40 CFR 798.5550<br>(modified) | rat, primary<br>hepatocytes             | <i>in vitro</i>                           | 0.251-10.0 µg/mL  | Not applicable                  | The test material showed no evidence of unscheduled DNA synthesis (UDS).  | 53 FR 27564; 7/21/88<br>Fiche# OTS0517692     |

## Results of Testing

| Chemical Name    | CAS No.  | Study Code/Type                                     | Protocol/Guideline            | Species                                 | Exposure                                  | Dose/Concentration  | No. per Group                   | Results   | Reference                                     |
|------------------|----------|---|-------------------------------|---|---|---|---------------------------------|---|---|
| <i>m</i> -Cresol | 108-39-4 | HEGTOXMUTA<br>Mutagenicity study                    | 40 CFR 798.5375<br>(modified) | mouse L5178Y<br>TK +/-                  | <i>in vitro</i>                           | 6.39-818 µg/mL<br>(nonactivated)<br>0.128-40.9 µg/mL<br>(activated) | Not applicable                  | None of the treatments caused increased mutant frequencies greater than 2-fold over the solvent control mutant frequency. The test materials were considered to have no genotoxic effects and were nonmutagenic either in the presence or absence of metabolic activation.  | 53 FR 27564; 7/21/88<br>Fiche# OTS0517693     |
| <i>m</i> -Cresol | 108-39-4 | HERTOXTERA<br>Developmental<br>toxicity             | 40 CFR 798.4900               | rats                                    | oral (gavage), days 6-<br>15 of gestation | 0, 30.0, 175.0,<br>450.0 mg/kg/d                                    | 25 pregnant<br>females          | At 450 mg/kg/day, there was a significant reduction in maternal body weight gain during the dosing period. At 450 mg/kg/day, clinical signs of toxicity were hypoactivity, ataxia, tremors, twitches, prone positioning, audible respiration, and peroral wetness. There were no significant changes in the incidence of any individual malformations for any dose group. | 53 FR 27564; 7/21/88<br>Fiche# OTS0517695     |
| <i>m</i> -Cresol | 108-39-4 | HERTOXTERA<br>Developmental<br>toxicity             | 40 CFR 798.4900               | rabbits                                 | oral (gavage), days 6-<br>18 of gestation | 0, 5.0, 50.0, 100.0<br>mg/kg/d                                      | 14 pregnant<br>females          | There were no treatment-related deaths, abortions, or early deliveries. Clinical signs of toxicity (audible respiration and ocular discharge) were observed at 50 and 100 mg/kg/day. There were no treatment-related effects on food consumption or incidence of any malformations.   | 53 FR 27564; 7/21/88<br>Fiche# OTS0517695     |
| <i>m</i> -Cresol | 108-39-4 | HERTOXTERE<br>2-Generation<br>reproduction study    | 40 CFR 798.4900<br>(modified) | rats                                    | gavage                                    | 0, 30, 175, 450 mg/kg<br>bw/day                                     | 25/sex/<br>generation/<br>group | No treatment related reproductive effects were observed in this 2-generation gavage study. The NOEL's for parental animals and offspring were 30 and 175 mg/kg bw/day, respectively.  | 54 FR 52449;<br>12/21/89 Fiche#<br>OTS0529224 |
| <i>o</i> -Cresol | 95-48-7  | HECTOXTRFM<br>Morphological<br>transformation study | 40 CFR 795.285<br>(modified)  | mice, BALB/C-<br>3T3 cells              | <i>in vitro</i>                           | 7.5-45 µL/mL  | Not applicable                  | The test material was found not to produce increased transformed foci, with or without activation. Cytotoxicity ranged from 7.2 to 87.8% over the test concentration range.   | 53 FR 37643; 9/27/88<br>Fiche# OTS0517697     |
| <i>o</i> -Cresol | 95-48-7  | HEGTOXCHRM<br>Rodent dominant<br>lethal assay       | 40 CFR 798.5450<br>(modified) | mice                                    | gavage                                    | 0, 75, 250, 750 mg/kg<br>bw   | 25/group                        | The treatment had no adverse effects with respect to number of early and late resorptions, and live implants, indicating that the test compound did not induce dominant lethal mutations in male germ cells of mice under the conditions of this assay.   | 54 FR 30460; 7/20/89<br>Fiche# OTS0529223     |
| <i>o</i> -Cresol | 95-48-7  | HEGTOXCHRM<br>Mammalian<br>cytogenicity study       | 40 CFR 798.5375<br>(modified) | Chinese<br>hamster ovary<br>cells (CHO) | <i>in vitro</i>                           | 10, 50, 250, 500, 749,<br>999 µg/mL                                 | Not applicable                  | The test materials did not induce chromosomal aberrations either in the presence or absence of metabolic activation.  | 53 FR 27564; 7/21/88<br>Fiche# OTS0517691     |
| <i>o</i> -Cresol | 95-48-7  | HEGTOXMUTA<br>Sex-linked recessive<br>lethal assay  | 40 CFR 798.5275<br>(modified) | <i>Drosophila<br/>melanogaster</i>      | oral (dietary), 3 d                       | 0, 100, 500, 1000<br>µg/mL  | 150/group                       | The treatment did not increase the frequency of sex-linked recessive lethal mutations, indicating that the test substance was not mutagenic in <i>Drosophila</i> under the conditions of this assay.  | 54 FR 14861; 4/13/89<br>Fiche# OTS0529221     |
| <i>o</i> -Cresol | 95-48-7  | HERTOXTERA<br>Developmental<br>toxicity             | 40 CFR 798.4900               | rabbits                                 | oral (gavage), days 6-<br>18 of gestation | 0, 5.0, 50.0, 100.0<br>mg/kg/d                                      | 14 pregnant<br>females          | There were no treatment-related deaths, abortions, or early deliveries. Clinical signs of toxicity (audible respiration and ocular discharge) were observed at 50 and 100 mg/kg/day. At 50 and 100 mg/kg/day hypoactivity was observed. There were no treatment-related effects on food consumption or incidence of any malformations.                                    | 53 FR 27564; 7/21/88<br>Fiche# OTS0517695     |

## Results of Testing

| Chemical Name    | CAS No.  | Study Code/Type   | Protocol/Guideline              | Species                           | Exposure   | Dose/Concentration                            | No. per Group                   | Results   | Reference                                     |
|------------------|----------|---|---------------------------------|-----------------------------------|--|---|---------------------------------|---|---|
| <i>o</i> -Cresol | 95-48-7  | HERTOXTERA<br>Developmental<br>toxicity   | 40 CFR 798.4900                 | rats                              | oral (gavage), days 6-15 of gestation  | 0, 30.0, 175.0, 450.0 mg/kg/d                 | 25 pregnant females             | At 450 mg/kg/day, there was a significant reduction in maternal body weight gain during the dosing period. At 450 mg/kg/day, clinical signs of toxicity were hypoactivity, ataxia, tremors, twitches, prone positioning, audible respiration, and peroral wetness. There were no significant changes in the incidence of any individual malformations for any dose group.   | 53 FR 27564; 7/21/88<br>Fiche# OTS0517695     |
| <i>o</i> -Cresol | 95-48-7  | HERTOXTERE<br>2-Generation<br>reproduction study                                | 40 CFR 798.4900 (modified)      | rats                              | gavage   | 0, 30, 175, 450 mg/kg bw/day                  | 25/sex/<br>generation/<br>group | No treatment related reproductive effects were observed in this 2-generation gavage study. The NOEL's for parental animals and offspring were 30 and 175 mg/kg bw/day, respectively.  | 54 FR 52449;<br>12/21/89 Fiche#<br>OTS0529224 |
| 2-Phenoxyethanol | 122-99-6 | HEATOX<br>Acute dermal toxicity<br>(Voluntary test)                             | Non-TSCA Protocol/<br>Guideline | rabbits                           | dermal; days 6-18 of gestation   | 0, 300, 600, 1000 mg/kg/d                     | 9 pregnant females              | Slight loss of body weight was seen in the 1000 mg/kg/day group. Gross pathological observations revealed no treatment-related effects.   | 49 FR 30114; 7/26/84<br>Fiche# OTS0507491     |
| 2-Phenoxyethanol | 122-99-6 | HEDSEN<br>Repeated insult patch<br>test<br>(Voluntary test)                     | Non-TSCA Protocol/<br>Guideline | human                             | dermal, occlusive patch; induction period of 24 hr/application; 3x/wk; 3 wks followed by a 10 to 15-day rest period, then by one 24-hr challenge application | 0.3 ml of a 10% (v/v) solution in mineral oil | 51 (completed study)            | No evidence of cumulative irritation or delayed contact sensitization was observed.   | 52 FR 27452; 7/21/87<br>Fiche# OTS0531472     |
| 2-Phenoxyethanol | 122-99-6 | HEGTOXMUTA<br>Forward mutation<br>assay<br>(Voluntary test)                     | Non-TSCA Protocol/<br>Guideline | Chinese hamster ovary (CHO) cells | <i>in vitro</i>  | 62.6, 125, 250, 500.0, 1000, 2500, 5000 µg/L  | Not applicable                  | No significant increases in mutation frequencies were noted in the presence or absence of exogenous metabolic activation.   | 52 FR 39560;<br>10/22/87<br>Fiche# OTS0531473 |
| 2-Phenoxyethanol | 122-99-6 | HERTOXTERA<br>Developmental<br>toxicity definitive<br>study<br>(Voluntary test) | Non-TSCA Protocol/<br>Guideline | rabbits                           | dermal, under occlusion; gestation days 6 through 18   | 300, 600, 1000 mg/kg/d                        | 10 females                      | Nine high-dose and 5 mid-dose rabbits died or were sacrificed in extremis following 5 to 13 applications. Most exhibited hemoglobinuria, pale livers, dark kidneys, and dark urine in the bladder. No information was provided regarding embryotoxicity in the surviving dam.   | 50 FR 31919; 8/07/85<br>Fiche# OTS0531469     |
| 2-Phenoxyethanol | 122-99-6 | HERTOXTERA<br>Developmental<br>toxicity definitive<br>study<br>(Voluntary test) | Non-TSCA Protocol/<br>Guideline | rabbits                           | dermal under occlusion; gestation days 6 through 18  | 300, 600, 1000 mg/kg/d                        | 25 females                      | Maternal toxicity (death of 9 and 5, respectively) was seen at high- and mid-dose. These animals had dark urine, were jaundiced, and exhibited dark kidneys. Stomach lesions were also seen in these animals. Surviving dams at these dose levels and at 300 mg/kg/day showed no evidence of treatment-related effects. No evidence of embryotoxicity, fetotoxicity, or teratogenicity was noted at any dose level. | 52 FR 2152; 1/20/87<br>Fiche# OTS0531468      |
| 2-Phenoxyethanol | 122-99-6 | HERTOXTERA<br>Developmental<br>toxicity probe study<br>(Voluntary test)         | Non-TSCA Protocol/<br>Guideline | rabbits                           | dermal, under occlusion; gestation days 6 through 18   | 300, 600, 1000 mg/kg/d                        | 10 females                      | Maternal toxicity (weight loss) was noted in the high-dose group. No evidence of embryotoxicity was seen at any level.  | 49 FR 30114; 7/26/84<br>Fiche# OTS0531469     |

## Results of Testing

| Chemical Name                     | CAS No.  | Study Code/Type  | Protocol/Guideline              | Species   | Exposure                          | Dose/Concentration                                     | No. per Group              | Results   | Reference                                |
|-----------------------------------|----------|--|---------------------------------|---|-----------------------------------|--|----------------------------|---|--|
| 2-Phenoxyethanol                  | 122-99-6 | HESTOX<br>Oral hemolytic anemia<br>(Voluntary test)      | Non-TSCA Protocol/<br>Guideline | rabbits   | oral gavage; up to<br>11 days     | 100, 300, 600, 1000<br>mg/kg/d                         | 3 females                  | Dose-related intravascular hemolytic anemia was noted (decreased RBC count, packed cell volume, and hemoglobin; hemoglobinuria; splenic congestion; renal tubule damage; and regenerative erythroid response in bone marrow and spleen).  | 52 FR 2152; 1/20/87<br>Fiche# OTS0531470 |
| 2-Phenoxyethanol                  | 122-99-6 | HESTOX<br>Subchronic dermal<br>study<br>(Voluntary test) | Non-TSCA Protocol/<br>Guideline | rabbits   | dermal; 6 hr/d, 5 d/wk,<br>13 wks | 50, 150, 500 mg/kg/d                                   | 10/sex                     | No mortalities occurred; no signs of systemic toxicity were noted. Sporadic occurrences of dermal erythema and very slight scaling were seen in the high-dose group. The NOEL (systemic toxicity) was 500 mg/kg/day.  | 52 FR 2152; 1/20/87<br>Fiche# OTS0531471 |
| 2-Phenoxyethanol                  | 122-99-6 | HESTOX<br>Oral hemolytic anemia<br>(Voluntary test)      | Non-TSCA Protocol/<br>Guideline | rats  | oral gavage; up to<br>14 days     | 1250, 2500 mg/kg/d                                     | 3 females                  | No overt signs of hemolysis were noted. A decrease in packed cell volume was seen in one low-dose rat. Signs of toxicity included lethargy and ataxia (low-dose), and loss of consciousness (high-dose).  | 52 FR 2152; 1/20/87<br>Fiche# OTS0531470 |
| 2,6-Di- <i>tert</i> -butyl-phenol | 128-39-2 | EEATOX<br>Acute toxicity                                 | 40 CFR 797.1050<br>(modified)   | <i>Selenastrum<br/>capricornutum</i><br>(freshwater<br>algae) | static, 96 hr                     | 0.33, 0.63, 1.2, 2.1, 2.9,<br>7.2 mg/L (measured)      | Not applicable             | Reduction in cell density after 24, 48, 72, and 96 hours of exposure (relative to control). The 96-hour EC <sub>50</sub> was determined to be 3.9 mg/L (initial) and 1.2 mg/L (TWA). The 96-hour NOEC was determined to be 2.1 mg/L (initial) and 0.64 mg/L (TWA).  | Fiche# OTS0534319                        |
| 2,6-Di- <i>tert</i> -butyl-phenol | 128-39-2 | EEATOX<br>Acute toxicity                                 | 40 CFR 797.1400<br>(modified)   | <i>Salmo<br/>gairdneri</i><br>(rainbow trout)                 | flow-through, 14 days             | 0, 0.27, 0.41, 0.63, 0.98,<br>1.5 mg/L                 | 20/group                   | Following 14 days of testing, 95% of the fish exposed to the highest test concentration died. At test termination (day 14), 20, 65, 10, and 20% mortality was observed at 0.27, 0.41, 0.63, and 0.98 mg/L, respectively. The 14-day LC <sub>50</sub> was estimated to be 0.74 mg/L. The test substance does not appear to be chronically toxic to rainbow trout. The NOEC was determined to be < 0.21 mg/L (lowest tested concentration). | Fiche# OTS0526680                        |
| 2,6-Di- <i>tert</i> -butyl-phenol | 128-39-2 | EEATOX<br>Acute toxicity                                 | 40 CFR 797.1400<br>(modified)   | <i>Pimephales<br/>promelas</i><br>(fathead<br>minnow)         | flow-through, 14 days             | 0, 0.30, 0.38, 0.60, 0.85,<br>1.4 mg/L (measured)      | 20/group                   | All fish exposed to 1.4 mg/L died within the initial 9 days of the test. At test termination (day 14) 15% mortality was observed at 0.85 mg/L while no mortalities occurred at the remaining treatment levels. The 14-day LC <sub>50</sub> was estimated to be 1.0 mg/L. The test substance does not appear to be chronically toxic to fathead minnows. The NOEC for the 14-day study was 0.30 mg/L.                                      | Fiche# OTS0526678                        |
| 2,6-Di- <i>tert</i> -butyl-phenol | 128-39-2 | EEATOX<br>Acute toxicity                                 | 40 CFR 797.1310                 | <i>Gammarus<br/>fasciatus</i><br>(gammarus)                   | flow-through, 4 day               | 0, 0.23, 0.38, 0.54, 0.80,<br>1.1 mg/L (measured)      | 20/group                   | Following 96 hours of exposure, 100, 85, and 30% mortality was observed at 1.1, 0.80, and 0.54 mg/L, respectively. Mortalities of <10% was observed at the remaining treatment levels. The 96-hour LC <sub>50</sub> value was determined to be 0.60 mg/L and the NOEC value was 0.38 mg/L.  | Fiche# OTS0526678                        |
| 2,6-Di- <i>tert</i> -butyl-phenol | 128-39-2 | EEATOX<br>Acute toxicity                                 | 40 CFR 797.1300                 | <i>Daphnia<br/>magna</i>                                      | 48 hr                             | 0, 0.076, 0.14, 0.21,<br>0.38, 0.59 mg/L<br>(measured) | 20/group<br>(10/replicate) | At 1.0 mg/L, all daphnids were immobilized after 48-hours. Immobilization of <10% was observed at the remaining concentrations, however, treatment-related sublethal effects were observed at levels >0.14 mg/L. The 48-hour EC <sub>50</sub> value was determined to be 0.45 mg/L and the NOEC was determined to be 0.76 mg/L.   | Fiche# OTS0526678                        |



## Results of Testing

| Chemical Name                     | CAS No.  | Study Code/Type                      | Protocol/Guideline                | Species                 | Exposure   | Dose/Concentration  | No. per Group        | Results   | Reference                                |
|-----------------------------------|----------|--------------------------------------|-----------------------------------|-------------------------|--|---|----------------------|---|--|
| 2,6-Di- <i>tert</i> -butyl-phenol | 128-39-2 | EFADEGPHOT<br>Photolysis             | 40 CFR 796.3765                   | Not applicable          | Sunlight, synthetic humic water and pure water (pH 7.0 buffer) | Not applicable  | Not applicable       | The effect of sunlight on the degradation of aqueous solutions of the test substance in synthetic humic water (SHW) and pure water (PW) (pH 7.0 buffer) was investigated. The ratio (Kp)SHW / (Kp)PW was 1.36 and suggest that the test substance is marginally susceptible to indirect photolysis.   | Fiche# OTS0544324                        |
| 2,6-Di- <i>tert</i> -butyl-phenol | 128-39-2 | EFBDEG<br>Anaerobic Biodegradability | 40 CFR 796.3140                   | Not applicable          | anaerobic, primary sludge inoculum, 56 days                    | 63 mg/L   | Not applicable       | The test substance did not degrade under the conditions of this study.  | Fiche# OTS0544324                        |
| 2,6-Di- <i>tert</i> -butyl-phenol | 128-39-2 | EFPCHVPRE<br>Vapor pressure          | Non-TSCA Protocol/<br>Guideline   | Not applicable          | 20° C  | Not applicable  | Not applicable       | The spiking levels and mean percent desorption efficiencies were as follows: 0.0565 mg, 86.2%; 0.113 mg, 86.0%; 0.170 mg, 84.4%. The vapor pressure at the different flow rates showed no significant (>5%) differences. The flow rates and calculated vapor pressures were as follows: 14.2 mL/min, 0.0073 mmHg; 25.9 mL/min, 0.0076 mmHg; 34.6 mL/min, 0.0079 mmHg.   | Fiche# OTS0526677                        |
| 2,6-Di- <i>tert</i> -butyl-phenol | 128-39-2 | EFPCHWSOL<br>Water solubility        | 40 CFR 796.1860                   | Not applicable          | Column generator, pH 5, 7, and 9                               | Not applicable  | Not applicable       | The water solubility of the test substance in water at pH 5, 7, and 9 was determined to be 3.99, 4.11, and 4.69 mg/L, respectively.   | Fiche# OTS0526677                        |
| Hexachlorocyclopentadiene         | 77-47-4  | HECTOXCARC<br>Carcinogenicity study  | National Toxicology Program (NTP) | F344/N rats             | inhalation, 2 yr   | 0, 0.01, 0.05, and 0.2 ppm (0, 0.11, 0.56, and 2.28 mg/m <sup>3</sup> ) | 60 male<br>60 female | No evidence of carcinogenic activity in male or female rats at any dose level. Exposure produced pigmentation of the respiratory epithelium of the nose, trachea (males), and bronchi and bronchioles of the lung. Squamous metaplasia of the laryngeal epithelium occurred in exposed female rats.   | TR-437, Feb. 1994, NTIS PB94-214186      |
| Hexachlorocyclopentadiene         | 77-47-4  | HECTOXCARC<br>Carcinogenicity study  | NTP                               | B6C3F <sub>1</sub> mice | inhalation, 2 yr   | 0, 0.01, 0.05, and 0.2 ppm (0, 0.11, 0.56, and 2.28 mg/m <sup>3</sup> ) | 60 male<br>60 female | No evidence of carcinogenic activity in male or female rats at any dose level. Suppurative inflammation of the nose as well as pigmentation of the respiratory mucosal epithelium occurred in exposed male mice.  | TR-437, Feb. 1994, NTIS PB94-214186      |
| 2-Ethylhexanoic Acid              | 149-57-5 | HEADME<br>Pharmacokinetic study      | 40 CFR 795.223 (modified)         | rats                    | dermal, single   | 100, 1000 mg/kg   | 4-8 females          | Peak blood levels of 8.1 µg equivalents/g blood were detected at 5.7 hours. Absorption half-life was 3.2 hours. Elimination was biphasic with half-lives of 4.2 and 251 hours. 42% and 46% were of the low and high doses were excreted in the urine, and 8% and 7% in the feces within 96 hours. The primary urinary metabolites were glucuronic acid conjugate of EHA, 2-ethyl hexanedioic acid, isomers of hydroxy-2-ethylhexanoic acid, and 2-lactones. | 53 FR 951; 1/14/88<br>Fiche# OTS05255471 |
| 2-Ethylhexanoic Acid              | 149-57-5 | HEADME<br>Pharmacokinetic study      | 40 CFR 795.223 (modified)         | rats                    | oral (gavage), single dose                                     | 100, 1000 mg/kg   | 4-8 females          | Peak blood levels of 85.1 µg equivalents/g blood were reached within 15-30 minutes; terminal half-life was 98 hours. Urinary excretion accounted for 79.3% and 82.3% for low and high doses, respectively, and in the feces, 12.4% and 6.7% within 96 hours. The primary urinary metabolites were glucuronic acid conjugate of EHA, 2-ethyl hexanedioic acid, isomers of hydroxy-2-ethylhexanoic acid, and 2-lactones.                                      | 53 FR 951; 1/14/88<br>Fiche# OTS05255471 |

## Results of Testing

| Chemical Name        | CAS No.   | Study Code/Type                         | Protocol/Guideline  | Species        | Exposure   | Dose/Concentration   | No. per Group   | Results  | Reference                                 |
|----------------------|-----------|---|---|----------------|--|--|-----------------|--|---|
| 2-Ethylhexanoic Acid | 149-57-5  | HEATOX<br>Acute oral toxicity           | Non-TSCA Protocol/<br>Guideline                                 | rats           | oral (gavage)  | 0, 90, 722, 1445, 2890<br>mg/kg bw/day                                     | 4/group         | All rats treated with 2890 mg/kg died on day 1. The remaining rats survived the 14-day observation period. Rats given 722 mg/kg or higher exhibited weakness on the day of dosing. Weight loss was observed in 14/16 during the first 24-hours, but by day 7 all had regained and exceeded their original weight. Absolute and relative liver weight of surviving rats did not differ from controls. An LD <sub>50</sub> of 2043 mg/kg was calculated. | 52 FR 27452; 7/21/87<br>Fiche# OTS0525538 |
| 2-Ethylhexanoic Acid | 149-57-5  | HERTOXTERA<br>Developmental<br>toxicity | 40 CFR 798.4900<br>(modified)                                   | rats           | oral (gavage),<br>gestation days 6-15  | 0, 100, 250, 500<br>mg/kg/d  | 25 bred females | High-dose dams had decreased body weight gain and food consumption, and clinical signs including ataxia, hypoactivity, and coughing. Mid- and high-dose fetuses had increased incidences of skeletal and visceral variations. Noels for maternal and developmental toxicity were 250 and 100 mg/kg/day, respectively.  | 53 FR 25662; 7/8/88<br>Fiche# OTS0525548  |
| 2-Ethylhexanoic Acid | 149-57-5  | HERTOXTERA<br>Developmental<br>toxicity | 40 CFR 798.4900<br>(modified)                                   | rabbits        | oral (gavage),<br>gestation days 6-18  | 0, 25, 125, 250 mg/kg/d  | 15 bred females | Maternal toxicity (abortion) occurred at 125 mg/kg/day, and mortality, decreased weight gain and clinical signs were noted in the high-dose group. No evidence of embryotoxicity, fetotoxicity, or teratogenicity was noted at any treatment level.  | 53 FR 25662; 7/8/88<br>Fiche# OTS0525548  |
| 2-Ethylhexanoic Acid | 149-57-5  | HESTOX<br>Subchronic toxicity           | 40 CFR 795.260<br>(modified)                                    | rats           | oral (dietary), 90 day   | 0, 61, 303, 917 mg/kg/d (males);<br>0, 71, 360, 1068 mg/kg/d (females)     | 10/sex          | Growth was retarded at the high dose level. Increased liver weight and histologic changes were noted at mid and high doses, along with slight hematologic differences. The no-adverse-effect-level was 303 mg/kg/day (males) and 360 mg/kg/day (females).  | 53 FR 25662; 7/8/88<br>Fiche# OTS0525548  |
| 2-Ethylhexanoic Acid | 149-57-5  | HESTOX<br>Subchronic toxicity           | 40 CFR 795.260<br>(modified)                                    | mice           | oral (dietary), 90 day   | 0, 180, 885, 2728 mg/kg/d (males);<br>0, 205, 1038, 3139 mg/kg/d (females) | 10/sex          | No mortalities occurred. High-dose animals had reduced body weights and feed intake, increased absolute and relative liver and kidney weights, decreased absolute and relative adrenal gland and absolute brain weight, and increased relative brain weight. Dose-related altered urea nitrogen and cholesterol levels were seen. Treatment-related histologic changes were seen in the liver, kidney and stomach.                                     | 53 FR 25662; 7/8/88<br>Fiche# OTS0525548  |
| Antimony trioxide    | 1309-64-4 | EFTSPT<br>Soil mobility                 | Non-TSCA<br>Protocol/Guideline<br>(see docket #<br>OPTS-42021A) | Not applicable | sand, clay, sandy and<br>silt loams, thin layer<br>chromatography<br>(TLC) plates, 24 hr | 100 µL   | Not applicable  | There was no significant evidence of mobility in any of the soil types for antimony.   | 52 FR 2152; 1/20/87<br>Fiche# OTS0511117  |
| Antimony trioxide    | 1309-64-4 | EFTSPT<br>Sediment adsorption           | Non-TSCA<br>Protocol/Guideline<br>(see docket #<br>OPTS-42021A) | Not applicable | 6 applications of a<br>spike to 32 TLC plates<br>for a total of 192<br>spikes            | 100 µL   | Not applicable  | Under the experimental conditions used in this study, no systematic or even significant evidence for widespread mobility was detected in any of the soil types examined (clay, sandy-loam, silt-loam, or sand).  | 51 FR 27598; 8/1/86<br>Fiche# OTS0511117  |

## Results of Testing

| Chemical Name                       | CAS No.   | Study Code/Type  | Protocol/Guideline  | Species                  | Exposure  | Dose/Concentration   | No. per Group         | Results   | Reference                                |
|-------------------------------------|-----------|--|---|--------------------------|---|--|-----------------------|---|--|
| Antimony trioxide                   | 1309-64-4 | HESTOX<br>Subchronic study   | Non-TSCA<br>Protocol/Guideline<br>(see docket #<br>OPTS-42021A) | rats                     | inhalation, 6 hr/d;<br>5d/wk; 13 wk, 27 wk<br>recovery period | 0.2, 1.0, 5.0, 25.0<br>mg/m <sup>3</sup> (nominal)   | 50 male;<br>50 female | The 2 highest dose levels produced a decrease in mean body weights (both males and females), and aspartate aminotransferase values (males) compared to the controls. Increases in the incidence of corneal irregularities (with or without opacity) were exhibited by treated males and females and controls. Increases in lung discoloration, granulomatous inflammation or granulomas in the lungs, and number of pulmonary alveolar or intra-alveolar macrophages. There were no significant differences in either the treated or control groups in mortality, or hematology values.   | 51 FR 6468; 2/24/86<br>Fiche# OTS0511116 |
| Chloromethane                       | 74-87-3   | HERTOXTERE<br>2-Generation<br>reproduction study<br>(Voluntary test) | Non-TSCA Protocol/<br>Guideline                                 | rats                     | inhalation, 6 hr/d;<br>5d/wk; 10 wks                          | 0, 150, 475, 1500 ppm  | 40 male;<br>80 female | Body weight gain decreased relative to controls for animals dosed at 1500 ppm after 2 weeks of exposure and for all F0 animals after day 57. Observations of treated animals (in high-dose males) included severe testicular degeneration and granulomas in the epididymis. No litters were born to exposed or unexposed females mated to high-dose males, and fewer litters were born to mid-dose females. No differences were observed in litter size, sex ratio, pup viability, or pup growth (in mid- to low-dosed groups). Two weeks after exposure ceased, 5 out of 20 F0 males had regained the ability to sire normal litters versus 15 out of 20 of the F0 mid-dosed and control males. A trend towards decreased fertility was observed in mid-dose F1 pups compared to the low-dose and control groups after 10 weeks of exposure. | 49 FR 30114; 7/26/84<br>OTS0206500       |
| Tris(2-ethylhexyl)-<br>trimellitate | 3319-31-1 | EECTOX<br>Chronic aquatic<br>toxicity                                | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42040)     | <i>Daphnia<br/>magna</i> | flow-through; 21 days<br>(life-cycle)                         | 7.4, 12, 27, 48, 100 µg/L<br>(nominal)   | Not specified         | Analysis of survival after a 21 day exposure with the test material showed that there was no significant difference between the treated and the control groups. Survival rates in the study ranged from 90 to 100%.   | 51 FR 6468; 2/24/86<br>Fiche# OTS0510635 |
| Tris(2-ethylhexyl)-<br>trimellitate | 3319-31-1 | EFANAL<br>Analytical validation                                      | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42040)     | Not applicable           | GC analysis;<br>deionized water,<br>stream water, octanol     | 0.35-1049 µg/L<br>(deionized), 3.50-104.9<br>µg/L (stream), 0.0104-<br>10.0 µg/L (octanol) | Not applicable        | Results of the method validation study for the test material in deionized water showed a mean recovery of 99 ± 5.0%. Mean recovery of test material in stream water was calculated at 93 ± 3.5%. In octanol, the mean recovery was 97 ± 2.2%.   | 51 FR 6468; 2/24/86<br>Fiche# OTS0510634 |
| Tris(2-ethylhexyl)-<br>trimellitate | 3319-31-1 | EFBDEG<br>Biodegradation study                                       | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42040)     | Not applicable           | 28 days, shake flask  | 0.26 mg<br>equivalents/L   | Not applicable        | The half-life for ultimate degradation was greater than 28 days, and for primary degradation, less than 28 days.  | 51 FR 16203; 5/1/86<br>Fiche# OTS0510640 |
| Tris(2-ethylhexyl)-<br>trimellitate | 3319-31-1 | EFPCHEPART<br>Octanol/water<br>coefficient                           | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42040)     | Not applicable           | octanol/deionized<br>water at 25 °C                           | 0.04% (v/v)  | Not applicable        | The log P value for the test material was 4.35.   | 51 FR 16203; 5/1/86<br>Fiche# OTS0510638 |
| Tris(2-ethylhexyl)-<br>trimellitate | 3319-31-1 | EFPCHEWSOL<br>Water solubility                                       | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42040)     | Not applicable           | deionized water,<br>equilibrated for<br>24 h at 25 ± 2 °C     | Not applicable   | Not applicable        | Water solubility was 0.385 ± 0.0404 ppb.  | 51 FR 6468; 2/24/86<br>Fiche# OTS0510634 |

## Results of Testing

| Chemical Name                   | CAS No.   | Study Code/Type  | Protocol/Guideline                                    | Species                           | Exposure                             | Dose/Concentration  | No. per Group              | Results  | Reference                                  |
|---------------------------------|-----------|--|---|-----------------------------------|--------------------------------------|---|----------------------------|--|--|
| Tris(2-ethylhexyl)-trimellitate | 3319-31-1 | HEADME Adsorption and metabolism test                    | Non-TSCA Protocol/ Guideline (see docket #OPTS-42040) | rats                              | oral (gavage), single dose           | 100 mg/kg/body wt   | Not specified              | Approximately 75% of the dose was excreted unchanged in the feces, with 16% of the test material found in the urine and 1.9% was expired as <sup>14</sup> CO <sub>2</sub> . Radioactivity was excreted in the feces as unchanged tris(2-ethylhexyl)trimellitate (TEHT) (constituting 85% of the fecal radioactivity), mono-(2-ethylhexyl) (MEHT), and di-(2-ethylhexyl) trimellitate (DEHT), and as unidentified polar metabolites. Metabolites in the urine were identified as MEHT and metabolites of 2-ethylhexanol. Less than 0.6% of the dose remained in the tissues. Elimination of <sup>14</sup> CO <sub>2</sub> was biphasic with half-lives of 4.3 and 31 hours. Excretion of radioactivity in the urine was biphasic with half-lives of 3.4 and 42 hours. | 50 FR 5421; 2/6/85<br>Fiche# OTS0507501    |
| Tris(2-ethylhexyl)-trimellitate | 3319-31-1 | HEGTOXDNAF Unscheduled DNA synthesis                     | Non-TSCA Protocol/ Guideline (see docket #OPTS-42040) | rats, primary hepatocytes         | <i>in vitro</i>                      | 0, 250, 500, 1000, 2500, 3000, 4000, 5000 nL/mL                             | Not specified              | None of the test concentrations caused a significant increase in unscheduled DNA synthesis over the solvent (ethanol) control.   | 50 FR 31919; 8/7/85<br>Fiche# OTS0508501   |
| Tris(2-ethylhexyl)-trimellitate | 3319-31-1 | HEGTOXDNAF Unscheduled DNA synthesis                     | Non-TSCA Protocol/ Guideline (see docket #OPTS-42040) | rats, primary hepatocytes         | <i>in vitro</i>                      | 0, 250, 500, 1000, 2500, 3000, 4000, 5000 nL/mL                             | Not specified              | None of the test concentrations caused a significant increase in unscheduled DNA synthesis over the solvent (ethanol) control.   | 51 FR 27598; 8/1/86<br>Fiche# OTS0510641   |
| Tris(2-ethylhexyl)-trimellitate | 3319-31-1 | HEGTOXMUTA Mutations in dosed rat urine                  | Non-TSCA Protocol/ Guideline (see docket #OPTS-42040) | rats                              | oral (gavage); 15 days               | 2000 mg/kg/d  | Unreported number of males | Urine from rats dosed with test material was evaluated in Salmonella tester strains (TA98, TA100, TA1537, and TA1528) both in the presence and absence of Aroclor-induced rat liver S9 metabolic activation. Tests performed with pure test material were negative in the presence and absence of activation. The urine of rats treated with test material did not cause a positive response under any of the test conditions.   | 51 FR 6468; 2/24/86<br>OTS0206391          |
| Tris(2-ethylhexyl)-trimellitate | 3319-31-1 | HEGTOXMUTA Gene mutations                                | Non-TSCA Protocol/ Guideline (see docket #OPTS-42040) | CHO/HGPRT                         | <i>in vitro</i>                      | 5, 10, 20, 50, 100, 200 nL/mL   | Not applicable             | The test material did not induce dose-related increases in the mutation frequency relative to the solvent control (aqueous ethanol) in any of the tests. Preliminary cytotoxicity tests showed that the test material was not toxic to CHO cells at concentrations up to 5000 nL/mL with or without metabolic activation.  | 50 FR 46699; 11/12/85<br>Fiche# OTS0510642 |
| Tris(2-ethylhexyl)-trimellitate | 3319-31-1 | HESTOX Subchronic toxicity                               | Non-TSCA Protocol/ Guideline (see docket #OPTS-42040) | rats                              | oral (gavage); 5d/wk; 4wk            | 0, 1000 mg/kg/d   | 5 males                    | There were no statistically significant differences between the treated and the control test animals in the following areas: mortality, body weight, absolute and relative liver weights, clinical signs of toxicity, and gross necropsy findings. There was, however, a significant decrease in triglyceride values between the control and treated groups.   | 51 FR 6488; 3/24/86<br>Fiche# OTS0507501   |
| Oleylamine                      | 112-90-3  | HEGTOXCHRM Mammalian cytogenetics assay (voluntary test) | Non-TSCA Protocol/ Guideline                          | Chinese hamster ovary cells (CHO) | <i>in vitro</i>                      | 0.05 to 1.5 nL/mL (without activation); 0.6 to 20.0 nL/mL (with activation) | Not applicable             | No evidence of increased frequency of chromosomal aberrations was noted in any assay.  | 50 FR 31919; 8/7/85<br>Fiche# OTS0525401   |
| Oleylamine                      | 112-90-3  | HEGTOXCHRM Cytogenicity study                            | 40 CFR 798.5385 (modified)                            | mice                              | oral (gavage); single administration | 0, 500, 2500, 5000 mg/kg  | 5/sex                      | No evidence of increased chromosomal aberrations were seen at any treatment level.   | 54 FR 52449; 12/21/89<br>Fiche# OTS0525407 |

## Results of Testing

| Chemical Name           | CAS No.  | Study Code/Type   | Protocol/Guideline              | Species                                 | Exposure   | Dose/Concentration   | No. per Group   | Results   | Reference                                     |
|-------------------------|----------|---|---------------------------------|---|--|--|-----------------|---|---|
| Oleylamine              | 112-90-3 | HEGTOXMUTA<br>Mutagenicity study                            | 40 CFR 798.5300<br>(modified)   | mouse L5173Y<br>TK +/-                  | <i>in vitro</i>                                  | 0.13-0.32 nL/ml  | Not applicable  | No evidence of increased mutation frequencies was noted either in the presence or absence of metabolic activation.  | 54 FR 43482;<br>10/25/89<br>OTS0000391-1      |
| Oleylamine              | 112-90-3 | HEGTOXMUTA<br>Mutagenicity assay<br>(voluntary test)        | Non-TSCA Protocol/<br>Guideline | <i>Salmonella</i><br><i>typhimurium</i> | <i>in vitro</i>                                  | up to 20 µg/plate<br>(nonactivated)<br>up to 200 µg/plate<br>(activated)               | Not applicable  | The test material did not cause a positive response in any of the bacterial strains (TA98, TA100, TA1535, TA1537 and TA1538) either with or without activation.   | 50 FR 31919; 8/7/85<br>OTS0000391-0           |
| Oleylamine              | 112-90-3 | HEGTOXMUTA<br>Mutagenicity study<br>(voluntary test)        | Non-TSCA Protocol/<br>Guideline | Chinese<br>hamster ovary<br>cells (CHO) | <i>in vitro</i>                                  | 0, 0.1 to 2.0 nL/mL<br>(without activation); 5.0<br>to 10.0 nL/mL (with<br>activation) | Not applicable  | In the first trial, an increased frequency of mutations was seen at 2.0 nL/mL (without activation) and at 9.0 nL/mL (with activation). Two subsequent trials did not duplicate these results; no evidence of increased mutations was seen at any level.   | 50 FR 46699;<br>11/12/85<br>Fiche# OTS0525402 |
| Oleylamine              | 112-90-3 | HERTOXTERA<br>Developmental<br>toxicity                     | 40 CFR 798.4900<br>(modified)   | rabbits                                 | oral (gavage);<br>gestation days 6<br>through 18 | 0, 3, 10, 30 mg/kg/d   | 22 bred females | Dose-related maternal toxicity was noted in mid- and high-dose dams (clinical signs, decreased body weight gain, and food consumption). No evidence of embryotoxicity, fetotoxicity, or developmental toxicity was noted at any level. The maternal NOEL was 3 mg/kg/day, and the developmental NOEL was 30 mg/kg/day.  | 54 FR 52449;<br>12/21/89<br>Fiche# OTS0525408 |
| Oleylamine              | 112-90-3 | HERTOXTERA<br>Developmental<br>toxicity                     | 40 CFR 798.4900<br>(modified)   | rats                                    | oral (gavage);<br>gestation days 6<br>through 15 | 0, 10, 40, 80 mg/kg/d  | 28 bred females | Dose-related maternal toxicity was noted in mid- and high-dose dams (clinical signs, decreased body weight gain, and food consumption). No evidence of embryotoxicity, fetotoxicity, or developmental toxicity was noted at any level. The maternal NOEL was 10 mg/kg/day, and the developmental NOEL was 80 mg/kg/day.   | 54 FR 2449; 12/21/89<br>Fiche# OTS0525408     |
| Oleylamine              | 112-90-3 | HESTOX<br>Dermal range-finding<br>study<br>(voluntary test) | Non-TSCA Protocol/<br>Guideline | rats                                    | dermal; 5 d/wk, 2 wk                             | 0, 12.5, 62.5, 125<br>mg/kg/d in mineral oil   | 4/sex           | Application to shaved backs caused mild to moderate skin irritation at the low exposure, and moderate to severe irritation at higher levels. Rats in the mid- and high-dose groups showed sensitivity to touch and had reduced body weight gain.  | 50 FR 31919; 8/7/85<br>Fiche# OTS0525400      |
| 2-Mercaptobenzothiazole | 149-30-4 | EECTOX<br>Fish early life stage                             | 40 CFR 797.1600<br>(modified)   | Rainbow trout                           | 89 days (69 days post-hatch)                     | 0, 24, 48, 95, 190, 380<br>µg/L (nominal)  | Not specified   | Embryo viability in all concentrations ranged from 91 to 97%. Survival at the completion of the hatching period (day 31) in all concentrations ranged from 86% (380 µg/L) to 89% (24 µg/L). At termination, survival at all concentrations ranged from 90-95%. Larval length was the most sensitive indicator of toxicity, mean total length of larvae exposed to levels greater than 78 µg/L ranged from 51.3 - 52.0 mm and was significantly less than controls. The mean weight at the 380 µg/L level was 1.1582 g which was significantly reduced as compared to controls. The Maximum Acceptable Toxicant Concentration (MATC) was estimated to be greater than 41 µg/L and less than 78 µg/L. | 54 FR 46980; 11/8/89<br>Fiche# OTS0525082     |

## Results of Testing

| Chemical Name            | CAS No.  | Study Code/Type                                 | Protocol/Guideline         | Species              | Exposure   | Dose/Concentration                            | No. per Group         | Results  | Reference                                 |
|--------------------------|----------|---|----------------------------|----------------------|--|---|-----------------------|--|---|
| 2-Mercaptobenzo-thiazole | 149-30-4 | EECTOX<br>Chronic invertebrate toxicity         | 40 CFR 797.1330 (modified) | <i>Daphnia magna</i> | flow-through, 21 days                                  | 0, 31, 63, 130, 250, 500 µg/L (nominal)       | Not specified         | On day 21, survival at 500 µg/L was 58% which was significantly less than controls. Survival at the remaining concentrations ranged from 93 to 98%. The 21-day EC <sub>50</sub> was estimated to be greater than 470 µg/L. The cumulative number of offspring at concentrations less than 250 µg/L ranged from 89 to 138. The Maximum Acceptable Toxicant Concentration was estimated to be greater than 240 mg/L and less than 470 µg/L.  | 54 FR 46980; 11/8/89<br>Fiche# OTS0525082 |
| 2-Mercaptobenzo-thiazole | 149-30-4 | EFADEGPHOT<br>Indirect photolysis screening     | 40 CFR 796.3765            | Not applicable       | synthetic humic waste (SHW) and pure water (W), pH 7.0 | 400 µg/L of test substance; 20 mL of SHW or W | Not applicable        | The ratio of (kp)SHW/(kp)W is 1.113 and suggests that the test substance is marginally susceptible to indirect photolysis. The results clearly show that photolytic breakdown of the test substance occurs rapidly with half lives under one hour. The calculated half-lives are 27.4 minutes for synthetic humic water and 31.1 minutes for pure water. The test substance can be classified as "photolabile".  | 54 FR 46980; 11/8/89<br>Fiche# OTS0525082 |
| 2-Mercaptobenzo-thiazole | 149-30-4 | EFBDEG<br>Aerobic aquatic biodegradation        | 40 CFR 796.3100            | Not applicable       | 28 days  | 20 mg/L                                       | Not applicable        | Minor, but not statistically significant degradation of the test substance was detected. A mean of 0.1% of the initial <sup>14</sup> C-2-MBT added was recovered as radiolabeled CO <sub>2</sub> in potassium hydroxide (KOH) traps. A mean of 0.1% of the initial <sup>14</sup> C-2-MBT along with a microbial inhibitor was recovered as radiolabeled CO <sub>2</sub> in KOH traps. A mean of 78.4% of the initial radiolabeled glucose added was recovered in KOH traps as <sup>14</sup> CO <sub>2</sub> .  | 54 FR 46980; 11/8/89<br>Fiche# OTS0525082 |
| 2-Mercaptobenzo-thiazole | 149-30-4 | EFTSPT<br>Soil and sediment adsorption isotherm | 40 CFR 796.2750            | Not applicable       | 120 hr   | 16 µg/mL (nominal)                            | Not applicable        | Preliminary studies showed 120 hours incubation of aqueous phase with soils/sediments were necessary to reach equilibrium. Adsorption characteristics varied appreciably among the three soil types but were similar for the sediments. There was an apparent correlation with the cation exchange capacity and percent organic matter in the soils. Resultant Kd and Koc adsorption coefficients when compared to similar data from other compounds suggested that the test substance mobility was medium to low in soil and slight to immobile in sediments. | 54 FR 46980; 11/8/89<br>Fiche# OTS0525082 |
| 2-Mercaptobenzo-thiazole | 149-30-4 | HEADME<br>General metabolism (voluntary test)   | 40 CFR 798.7470 (modified) | rats                 | dermal (topical), 96 hr                                | 0.0361, 0.0336 mg/kg                          | 4 males;<br>4 females | More of the radioactive test material could be removed by washing the skin of guinea pigs than by washing the skin of rats. At 96 hours, 16.1 and 17.5% of the dose was absorbed by male and female rats, respectively. Male and female rats dosed topically with the test material excreted 11.9 and 13.4%, respectively, in the urine and 0.980 and 0.641% of the dose in the feces.   | 52 FR 13311; 4/22/87<br>Fiche# OTS0521671 |
| 2-Mercaptobenzo-thiazole | 149-30-4 | HEADME<br>General metabolism (voluntary test)   | 40 CFR 798.7470 (modified) | guinea pigs          | dermal (topical), 96 hr                                | 0.0361, 0.0336 mg/kg                          | 4 females             | More of the radioactive test material could be removed by washing the skin of guinea pigs than by washing the skin of rats. At 96 hours 38.4% of the dose was absorbed. Female guinea pigs dosed topically with the test material excreted 33.3% in the urine and 0.389% of the dose in the feces.   | 52 FR 13311; 4/22/87<br>Fiche# OTS0521671 |

## Results of Testing

| Chemical Name           | CAS No.  | Study Code/Type                                  | Protocol/Guideline                   | Species                 | Exposure  | Dose/Concentration                                      | No. per Group        | Results   | Reference                                     |
|-------------------------|----------|--|--------------------------------------|-------------------------|---|---|----------------------|---|---|
| 2-Mercaptobenzothiazole | 149-30-4 | HEADME<br>General metabolism<br>(voluntary test) | 40 CFR 798.7470<br>(modified)        | rats                    | oral (gavage), 96 hr  | 0.592, 55.5 mg/kg                                       | 4 male;<br>4 female  | High-dose test animals exposed to <sup>14</sup> C-MBT and <sup>14</sup> C MBTS (2-mercaptobenzothiazole and 2-mercaptobenzothiazole disulfide, respectively) excreted (within 96 hours) 72.1 to 106% of the administered dose in urine, and 4.03 to 10.3% was excreted in the feces. A small portion (0.423 to 2.04%) of the dose remained associated with the erythrocytes. Low-dosed animals retained a higher percent of the dose in whole blood and plasma than did the high-dose animals.  | 51 FR 39799;<br>10/31/86<br>Fiche# OTS0510971 |
| 2-Mercaptobenzothiazole | 149-30-4 | HECTOXCARC<br>Carcinogenicity study              | National Toxicology<br>Program (NTP) | F344/N rats             | gavage, 5 d/wk, 103 weeks   | 0, 375, 750 mg/kg<br>(male); 0, 188, 375 mg/kg (female) | 50 male<br>50 female | Some evidence of carcinogenicity for male rats indicated by increased incidences of mononuclear cell leukemia, pancreatic acinar cell adenomas, adrenal gland pheochromocytomas, and preputial gland adenomas or carcinomas (combined). Some evidence of carcinogenicity in female rats indicated by increased incidences of adrenal gland pheochromocytomas and pituitary gland adenomas.  | TR-332, May 1988,<br>NTIS PB88245154          |
| 2-Mercaptobenzothiazole | 149-30-4 | HECTOXCARC<br>Carcinogenicity study              | NTP                                  | B6C3F <sub>1</sub> mice | gavage, 5 d/wk, 103 weeks   | 0, 375, 750 mg/kg                                       | 50 male<br>50 female | No evidence of carcinogenicity in male mice at either dose. Equivocal evidence of carcinogenicity in female mice indicated by increased incidences of hepatocellular adenomas or carcinomas (combined).   | TR-332, May 1988,<br>NTIS PB88245154          |
| 2-Mercaptobenzothiazole | 149-30-4 | HEGTOXCHRM<br>Rodent dominant<br>lethal study    | 40 CFR 798.5450                      | rats                    | oral (diet), 13 weeks, followed by 2 weeks treatment during breeding period | 0, 2500, 8750, 15,000 ppm                               | 28/group             | Decreased body weight gain (all groups) and food consumption (mid- and high-groups) was observed. The treatment did not increase the incidence of embryonic deaths or decrease the number of viable embryos, indicating that the test compound was not mutagenic to germ cells in the male rat.   | 54 FR 46980; 11/8/89<br>Fiche# OTS0524631     |
| 2-Mercaptobenzothiazole | 149-30-4 | HENEUR<br>Neuropathology                         | 40 CFR 798.6400<br>(modified)        | rats                    | oral (dietary), 13 wks  | 0, 5000, 15,000, 25,000 ppm                             | 12/sex               | No gross or neuropathological effects were noted at any test level.   | 55 FR 19786; 5/11/90<br>Fiche# OTS0530505     |
| 2-Mercaptobenzothiazole | 149-30-4 | HENEUR<br>Motor activity                         | 40 CFR 798.6200<br>(modified)        | rats                    | oral (dietary), 13 wks  | 0, 5000, 15,000, 25,000 ppm                             | 12/sex               | No effects were noted on motor activity at any test level.  | 55 FR 19786; 5/11/90<br>Fiche# OTS0530505     |
| 2-Mercaptobenzothiazole | 149-30-4 | HENEUR<br>Functional<br>observational battery    | 40 CFR 798.6050<br>(modified)        | rats                    | oral (dietary), 13 wks  | 0, 5000, 15,000, 25,000 ppm                             | 12/sex               | No mortalities occurred. Reduced body weight were noted in high-dose males and in females at 15,000 ppm and higher, along with sporadic reductions in food intake. No effects were noted on grip strength or hind limb splay.   | 55 FR 19786; 5/11/90<br>Fiche# OTS0530505     |
| 2-Mercaptobenzothiazole | 149-30-4 | HERTOXTERA<br>Developmental<br>toxicity          | 40 CFR 798.4900                      | rats                    | oral (gavage),<br>gestation days 6-15                                       | 0, 300, 1200, 1800 mg/kg/day                            | 26/group             | Body weight gain and food intake were reduced in high-dose dams and clinical signs of toxicity (salivation, urine staining, and dark material around the mouth) were observed in mid- and high-dose dams. The treatment had no adverse effects with respect to fetal viability, body weights, sex ratio or incidence of external, visceral, or skeletal malformations for variations. Post-implantation loss was increased in the high-dose group. NOEL's for maternal and developmental toxicity were 300 and greater than 1800 mg/kg/day, respectively. | 54 FR 46980;<br>11/08/89 Fiche#<br>OTS0525082 |

## Results of Testing

| Chemical Name           | CAS No.   | Study Code/Type                                    | Protocol/Guideline            | Species           | Exposure   | Dose/Concentration           | No. per Group  | Results  | Reference                                     |
|-------------------------|-----------|--|-------------------------------|-------------------|--|------------------------------|----------------|--|---|
| 2-Mercaptobenzothiazole | 149-30-4  | HERTOXTERA<br>Developmental toxicity               | 40 CFR 798.4900               | rabbits           | oral (gavage),<br>gestation day 6-18   | 0, 50, 150, 300<br>mg/kg/day | 20/group       | Slight maternal toxicity (decreased relative liver weight) was observed in high-dose does. The treatment had no adverse effects with respect to survival, body weight gain, food intake, clinical signs, and gross morphology. There was no effect of treatment on fetal viability, body weights, or incidences of external, visceral, or skeletal malformations or variations. NOEL's for maternal and developmental toxicity were 150 and greater than 300 mg/kg/day, respectively.  | 54 FR 46980;<br>11/08/89<br>Fiche# OTS0525082 |
| 2-Mercaptobenzothiazole | 149-30-4  | HERTOXTERE<br>Reproductive toxicity                | 40 CFR 798.4700               | rats              | oral (dietary), at least<br>70 days prior to<br>mating, through 2<br>generations | 2,500, 8,750, 15,000<br>ppm  | 28/sex         | No mortalities occurred. Treatment-related decreased body weight gain was seen in males from all groups and in mid- and high-dose females. Body weights were reduced in mid- and high-dose F1 pups, and in all treatment-group F2 pups. Absolute and relative kidney weights were increased for F0 and F1 males in the two highest treatment groups. No effects were noted on reproductive indices.  | 54 FR 46980; 11/8/89<br>Fiche# OTS0530506     |
| 2-Mercaptobenzothiazole | 149-30-4  | HERTOXTERE<br>Reproductive toxicity                | 40 CFR 798.4700               | rats              | oral (dietary), at least<br>70 days prior to<br>mating, through 2<br>generations | 2,500, 8,750, 15,000<br>ppm  | 28/sex         | No mortalities occurred. Treatment-related decreased body weight gain was seen in males from all groups and in mid- and high-dose females. Body weights were reduced in mid- and high-dose F1 pups, and in all treatment-group F2 pups. Absolute and relative kidney weights were increased for F0 and F1 males in the two highest treatment groups. No effects were noted on reproductive indices.  | 54 FR 46980; 11/8/89<br>Fiche# OTS0530506     |
| C.I. Disperse Blue 79:1 | 3618-72-2 | HEADME<br>General metabolism                       | 40 CFR 798.7100<br>(modified) | rats              | oral (gavage)  | 50 mg/kg and 500 mg/kg       | 4/group/sex    | Greater than 73% of the administered dose was excreted in the feces within the first 24 hr and an additional fecal fraction of 5-12% was excreted in the following 24 hr. Of the total initial C-14 dose given, a total of 88% in males and 85% in females for the 50 mg/kg dose, and 91% in males and 86% in females for the 500 mg/kg dose, was excreted in the feces by 96 hr post-dosing.  | 54 FR 48102;<br>10/11/91<br>OTS533201         |
| C.I. Disperse Blue 79:1 | 3618-72-2 | HEGTOXMUTA<br>Sex linked recessive<br>lethal assay | 40 CFR 798.5275               | <i>Drosophila</i> | Injection  | 0.3 µL                       | Not specified  | The test substance was injected with approximately 0.3 µL at a concentration of 50 ppm in 1.9% DMSO and 0.1% Tween 80 carried in 0.7% aqueous saline. The test material was not toxic and no male sterility was induced. The sex-linked recessive lethal results show no differences between the treated samples and the negative controls. It was concluded that the test substance does not induce mutations in the post-meiotic germ cells of <i>Drosophila melanogaster</i> when administered by injection to adult males. | 55 FR 50055;<br>12/04/90 Fiche#<br>OTS0529345 |
| C.I. Disperse Blue 79:1 | 3618-72-2 | HERTOXTERA<br>Developmental toxicity               | 40 CFR 798.4900               | rats              | oral (gavage) in water<br>or corn oil, gestational<br>day 6-15                   | 5, 10 ml/kg/d                | 5/group        | Maternal weight gain was decreased in the corn oil treated groups. Average fetal body weight/litter was reduced and percent malformed fetuses/litter was increased when corn oil was used as the vehicle in treated groups.  | 56 FR 2178; 1/22/91<br>Fiche# OTS0529331      |
| C.I. Disperse Blue 79:1 | 3618-72-2 | HERTOXTERA<br>Developmental toxicity               | 40 CFR 798.4900               | mice              | oral (gavage) in water<br>or corn oil, gestational<br>d 6-15                     | 5, 10 ml/kg/d                | 5/vehicle/dose | No maternal effects were noted. The percent malformed fetuses/litter was significantly increased in litters when corn oil was used as the vehicle in treated groups.   | 56 FR 2178; 1/22/91<br>Fiche# OTS0529331      |



## Results of Testing

| Chemical Name                       | CAS No.   | Study Code/Type                      | Protocol/Guideline                                    | Species                                | Exposure   | Dose/Concentration                         | No. per Group     | Results  | Reference                                 |
|-------------------------------------|-----------|--------------------------------------|---|--|--|--|-------------------|--|---|
| C.I. Disperse Blue 79:1             | 3618-72-2 | HERTOXTERA<br>Developmental toxicity | 40 CFR 798.4900                                       | rabbits                                | oral (gavage), 1/d on gestation day 6-18                                     | 0.0, 100.0, 300.0, 600.0 mg/kg/d           | 16 mated/group    | Maternal toxicity at 300 and 600 mg/kg/day and a slight reduction in fetal body weight at 600 mg/kg/day. There was no evidence of teratogenicity at any dose tested. The "no observable adverse effect level" (NOAEL) for maternal toxicity was 300 mg/kg/day.   | 56 FR 24101; 5/29/91<br>OTS533199         |
| C.I. Disperse Blue 79:1             | 3618-72-2 | HESTOX<br>Subchronic oral toxicity   | 40 CFR 798.2650                                       | rats                                   | oral (gavage), 5 d/wk for 90 days  | 250, 1250, 2500 mg/kg/d                    | 10/group/sex      | The only observation related to the test substance over the 90-day study were blue coloration of the skin and/or tail of some animals. There were no treatment-related alterations in any other observations or measurements in either sex at any dose. The no observable effect level (NOEL) was at least 2500 mg/kg/day. | 56 FR 12202; 3/22/91<br>Fiche# OTS0529333 |
| 4-(1,1,3,3-Tetra-methylbutyl)phenol | 140-66-9  | EEATOX<br>Algae acute toxicity       | TSCA Protocol/Guideline (see docket # OPTS-42042)     | Green algae                            | static, 96 hr  | 1.0, 1.8, 3.2, 5.6, 10 mg/L (nominal)      | Not applicable    | The 96-hour no-observed-effect concentration was <1.0 mg/L. The study was performed following the TSCA guidelines for algal acute toxicity. The EC <sub>50</sub> for growth was 1.9 mg/L, with a 95% confidence interval of 1.0 to 2.7 mg/L.   | 50 FR 5421; 2/6/85<br>Fiche# OTS0507489   |
| 4-(1,1,3,3-Tetra-methylbutyl)phenol | 140-66-9  | EEATOX<br>Acute fish toxicity        | Non-TSCA Protocol/Guideline (see docket # OPTS-42042) | Fathead minnow                         | flow-through, 96 hr  | 0.041, 0.077, 0.15, 0.34, 0.63 mg/L        | 20                | The 96-hour LC <sub>50</sub> was 0.25 mg/L, with a corresponding 95% confidence interval of 0.15 to 0.34 mg/L. The no-observed-effect concentration was 0.077 mg/L. Surfacing, loss of equilibrium, dark discoloration, and quiescence were observed in the 0.18, 0.37, and 0.63 mg/L test concentrations.                 | 50 FR 5421; 2/6/85<br>Fiche# OTS0507489   |
| 4-(1,1,3,3-Tetra-methylbutyl)phenol | 140-66-9  | EEATOX<br>Acute fish toxicity        | Non-TSCA Protocol/Guideline (see docket # OPTS-42042) | <i>Salmo gairdneri</i> (Rainbow trout) | flow-through, 14 d   | 0.035, 0.084, 0.17, 0.32, 0.71 mg/L        | 20                | The 14-day no-observed-effect concentration was calculated to be 0.084 mg/L for the test material. The lethal threshold was reached on day 10 of the study, and was estimated to be 0.12 mg/L. The 95% confidence interval was 0.084 to 0.17 mg/L.   | 50 FR 5421; 2/6/85<br>Fiche# OTS0507489   |
| 4-(1,1,3,3-Tetra-methylbutyl)phenol | 140-66-9  | EEATOX<br>Acute daphnid toxicity     | Non-TSCA Protocol/Guideline (see docket # OPTS-42042) | <i>Daphnia magna</i>                   | flow-through, 48 hr  | 0.063, 0.11, 0.19, 0.32, 0.94 mg/L         | 10                | Based on lack of mortality and abnormal effects, the 48-hour no-observed-effect concentration was 0.11 mg/L for the test chemical. The LC <sub>50</sub> and its corresponding 95% confidence interval was 0.27 mg/L and 0.19 to 0.32 mg/L, respectively.   | 50 FR 5421; 2/6/85<br>Fiche# OTS0507489   |
| 4-(1,1,3,3-Tetra-methylbutyl)phenol | 140-66-9  | EECLIF<br>Early life stage toxicity  | Non-TSCA Protocol/Guideline (see docket # OPTS-42042) | <i>Salmo gairdneri</i> (Rainbow trout) | flow-through, 60 d post-hatch  | 0, 0.0061, 0.011, 0.022, 0.051, 0.091 mg/L | 80 (20/replicate) | Survival of fry and growth (wet weight) were reduced at 0.022 mg/L and higher; fry growth (length) was reduced at 0.011 and higher. The maximum acceptable toxicant concentration (MATC) was between 0.0061 and 0.11 mg/L. The NOEC was 0.0061 mg/L.   | 52 FR 2152; 1/20/87<br>Fiche# OTS0527139  |
| 4-(1,1,3,3-Tetra-methylbutyl)phenol | 140-66-9  | EFPCHEWSOL<br>Water solubility       | Non-TSCA Protocol/Guideline (see docket # OPTS-42042) | Not applicable                         | environmental chamber at 22 ± 2 °C, deionized water and natural water, 24 hr | 10 mL                                      | Not applicable    | Solubilities in deionized water and natural water determined as the mean of duplicate analyses, 3 consecutive samples, were 17 and 19 µg/mL, respectively.   | 50 FR 5421; 2/6/85<br>Fiche# OTS0527138   |

## Results of Testing

| Chemical Name       | CAS No.    | Study Code/Type   | Protocol/Guideline                                    | Species                              | Exposure  | Dose/Concentration                         | No. per Group                 | Results  | Reference   |
|---------------------|------------|---|---|--------------------------------------|---|--|-------------------------------|--|---|
| Calcium naphthenate | 61789-36-4 | HEDIRR<br>Sebaceous gland suppression test (voluntary test) | Non-TSCA Protocol/Guideline                           | mice                                 | epidermal application; duration not reported    | 0.2 mL (neat)                              | 30 females                    | Test animals were treated with 0, 1, 2, 3, 4, or 6 epidermal applications of the test material. The application of the test material (neat) induced active sebaceous gland suppression. Sebaceous glandular suppression rose quickly after 2 or 3 doses obtaining 88% suppression by the 4th application. Almost complete suppression (97%) was reached after the 6th application.   | 52 FR 13311; 5/22/87<br>Fiche# OTS0512234         |
| Calcium naphthenate | 61789-36-4 | HECTOXCARC<br>Carcinogenicity study (voluntary test)        | Non-TSCA Protocol/Guideline                           | mice                                 | epidermal application; 2x/d; 2 y                | 0.05 mL (neat)                             | 50 females                    | Clinical observations included mild irritation, hair loss, shiny patches on the skin, and flaking skin surfaces. This progressed to moderate irritation (observed with sores and scabs on the treated site), or severe irritation caused by large sores or visible ulcers. In the negative control group, no cutaneous tumors developed at or distant to treated sites. Twelve epidermal and one dermal tumor at the treated sites were observed in eight mice that were exposed to the test material. Four of the tumors were malignant and nine were benign. The first of these neoplasms were reported after 392 days of treatment. No metastatic tumors were present.  | 52 FR 13311; 5/22/87<br>Fiche# OTS0512234         |
| Calcium naphthenate | 61789-36-4 | HERTOX<br>1-Generation reproduction study (voluntary test)  | Non-TSCA Protocol/Guideline                           | rabbits                              | dermal; 6 h/d; 5d/wk; 10 wk; followed by mating | 2 mL (neat)                                | 10 males; 2 untreated females | There were no systemic toxicity, application site toxicity, or statistically significant changes in body weights observed in the test animals during the 10 week exposure period or the 12 week post-exposure period. In the male animals, there were no significant changes in testes weights. In the females, there were no significant differences in the number of implantations, or in pre- and post- implantation losses. In addition, there were no differences in viable fetuses to those females that were mated with exposed males compared to those mated with unexposed males. The study also reported that there were no macroscopic or microscopic pathological findings in the male reproductive tract. | 49 FR 30114; 7/26/84<br>Fiche# OTS0507494         |
| 4-Nitroaniline      | 100-01-6   | HEGTOXCHRM<br>Mammalian bone marrow micronucleus assay      | Non-TSCA Protocol/Guideline (see docket #OPTS-42054B) | mice                                 | intraperitoneal injection, 2x, 24 hours apart   | 0, 80, 400, 800 mg/kg/day                  | 5 to 6/sex                    | No evidence of clastogenicity was found in any treatment group.  | 777277254 FR 42034; 10/13/89<br>Fiche# OTS0532109 |
| 4-Chloroaniline     | 106-47-8   | HEGTOXCHRM<br>Mammalian bone marrow micronucleus assay      | Non-TSCA Protocol/Guideline (see docket #OPTS-42054B) | mice                                 | oral (gavage), single dose                      | 0, 50, 100, 200 mg/kg body weight          | 5 male; 5 female              | The incidence of micronucleated polychromatic erythrocytes in the test animals treated with 4-chloroaniline were within normal range. The number of normochromatic erythrocytes containing micronuclei was not increased. The ratio of polychromatic/normochromatic erythrocytes in both male and female test animals remained unaffected. Results indicated that the test material was not mutagenic.   | 53 FR 45385; 11/9/88<br>Fiche# OTS0519119         |
| Aniline             | 62-53-3    | EEATOX<br>Acute aquatic invertebrate toxicity               | Non-TSCA Protocol/Guideline (see docket #OPTS-42054B) | <i>Gammarus fasciatus</i> (amphipod) | flow-through, 96 hr                             | 0.18, 0.38, 0.70, 1.4, 2.7 mg/L (measured) | 20 (10/replicate)             | Exposure of the test animals to the test material (aniline) resulted in a 96-hour LC <sub>50</sub> of 2.3 mg/L (1.9 to 3.1 mg/L). The no-observed-effect concentration (NOEC) based on survival was 1.4 mg/L.  | 54 FR 25167; 6/13/89<br>Fiche# OTS0519116         |

## Results of Testing

| Chemical Name   | CAS No. | Study Code/Type  | Protocol/Guideline                                    | Species                              | Exposure                                      | Dose/Concentration                        | No. per Group                   | Results   | Reference                                  |
|-----------------|---------|--|---|--------------------------------------|---|---|---------------------------------|---|--|
| Aniline         | 62-53-3 | EECTOX<br>Chronic aquatic toxicity - crustacean        | Non-TSCA Protocol/Guideline (see docket #OPTS-42054B) | <i>Daphnia magna</i>                 | flow-through, 21 d                            | 0.006-0.040 (measured)                    | 20 (10/replicate)               | No effects were noted at 0.016 mg/L. At 0.027 mg/L and higher, reproduction was significantly decreased as compared to controls. The maximum allowable toxicant concentration (MATC) was 0.021 mg/L.  | 54 FR 33772; 8/16/89<br>Fiche# OTS0532105  |
| Aniline         | 62-53-3 | EECTOX<br>Chronic aquatic toxicity - crustacean        | Non-TSCA Protocol/Guideline (see docket #OPTS-42054B) | <i>Daphnia magna</i>                 | flow-through, 21 d                            | 0.006-0.040 mg/L                          | 20 (10/replicate)               | Decreased reproduction occurred at 0.027 mg/L and higher. No effects were noted at 0.016 mg/L. The MATC was 0.021 mg/L, measured concentration.   | 54 FR 33773; 8/16/89<br>Fiche# OTS0532105  |
| Aniline         | 62-53-3 | HEGTOXCHRM<br>Mammalian bone marrow micronucleus assay | Non-TSCA Protocol/Guideline (see docket #OPTS-42054B) | mice                                 | intraperitoneal injection, 2x, 24 hours apart | 0, 30, 100, 300 mg/kg/day                 | 3/sex                           | Increased incidence of micronucleated polychromatic erythrocytes were seen in the high dose groups for both sexes.  | 54 FR 33773; 8/16/89<br>Fiche# OTS0532103  |
| 2-Nitroaniline  | 88-74-4 | HEGTOXCHRM<br>Mammalian bone marrow micronucleus assay | Non-TSCA Protocol/Guideline (see docket #OPTS-42054B) | mice                                 | intraperitoneal injection, 2x, 24 hours apart | 0, 50, 250, 500 mg/kg/day                 | 5 to 6/sex                      | No evidence of clastogenicity was noted in any dose group.  | 54 FR 42034; 10/13/89<br>Fiche# OTS0532108 |
| 2-Chloroaniline | 95-51-2 | EEATOX<br>Acute fish toxicity                          | Non-TSCA Protocol/Guideline (see docket #OPTS-42054B) | Rainbow trout                        | flow-through, 96 hr                           | 0.30, 0.58, 1.1, 2.0, 4.3 mg/L (measured) | 20 (10/replicate)               | The test material had an LC <sub>50</sub> value (and a 95% confidence limit) of 1.0 mg/L (0.82 to 1.4 mg/L). Altered body coloration and erratic swimming were noted.   | 54 FR 25167; 6/13/89<br>Fiche# OTS0519118  |
| 2-Chloroaniline | 95-51-2 | EEATOX<br>Acute invertebrate toxicity                  | Non-TSCA Protocol/Guideline (see docket #OPTS-42054B) | <i>Gammarus fasciatus</i> (amphipod) | flow-through, 96 hr                           | 0, 0.72, 1.2, 2.0, 3.8, 8.2 mg/L          | Not specified                   | Exposure to the test material resulted in a 96-hour LC <sub>50</sub> value of 5.4 mg/L (2.9 to 0.62 mg/L). The no-observed-effect concentration based on survival was 3.8 mg/L. Test animals exposed to 8.2 mg/L exhibited lethargy and immobilization. | 54 FR 25167; 6/13/89<br>Fiche# OTS0519118  |
| 2-Chloroaniline | 95-51-2 | EECLIF<br>Fish early life stage test                   | Non-TSCA Protocol/Guideline (see docket #OPTS-42054B) | rainbow trout                        | flow-through, 105 d                           | 0.0037-1.4 mg/L                           | 60/concentration (30/replicate) | The NOEC was 0.0037 mg/L, and the lowest effect concentration was 0.012 mg/L (growth in length). The MATC was 0.0067 mg/L.  | 54 FR 33772; 8/16/89<br>Fiche# OTS0532104  |
| 2-Chloroaniline | 95-51-2 | EECTOX<br>Chronic aquatic toxicity - crustacean        | Non-TSCA Protocol/Guideline (see docket #OPTS-42054B) | <i>Daphnia magna</i>                 | static, 21 d                                  | 0.013-0.19 mg/L                           | Not specified                   | Survival was decreased at 0.19 mg/L, and at 0.046 mg/L and higher, decreased total young produced and offspring per surviving adult was noted.  | 54 FR 33773; 8/16/89<br>Fiche# OTS0532104  |
| 2-Chloroaniline | 95-51-2 | EECTOX<br>Chronic aquatic toxicity - crustacean        | Non-TSCA Protocol/Guideline (see docket #OPTS-42054B) | <i>Daphnia magna</i>                 | flow-through, 21 d                            | 0.013-0.19 mg/L (measured)                | 10 (10/replicate)               | The no-effect level was 0.025 mg/L. At 0.19 mg/L, survival was significantly decreased over controls, and at 0.046 mg/L and higher reproduction was decreased. The MATC was 0.025 mg/L.   | 54 FR 33772; 8/16/89<br>Fiche# OTS0532104  |
| 2-Chloroaniline | 95-51-2 | HEGTOXCHRM<br>Mammalian bone marrow micronucleus assay | Non-TSCA Protocol/Guideline (see docket #OPTS-42054B) | mice                                 | intraperitoneal injection, 2x, 24 hours apart | 0, 20, 70, 200 mg/kg/day                  | 4 or 5/sex                      | No evidence of increased micronucleated polychromatic erythrocytes were seen at any test level.   | 54 FR 39806; 9/28/89<br>Fiche# OTS0532107  |

## Results of Testing

| Chemical Name               | CAS No.  | Study Code/Type   | Protocol/Guideline                                    | Species                                  | Exposure                                      | Dose/Concentration                      | No. per Group     | Results   | Reference                                   |
|-----------------------------|----------|---|---|--|---|---|-------------------|---|---|
| 3,4-Dichloroaniline         | 95-76-1  | HEGTOXCHRM<br>Mammalian bone marrow micronucleus assay          | Non-TSCA Protocol/Guideline (see docket #OPTS-42054B) | mice                                     | intraperitoneal injection, 2x, 24 hours apart | 0, 20, 70, 200 mg/kg/day                | 5/sex             | No evidence of clastogenicity was found in any treatment group.   | 54 FR 43482; 10/25/89<br>Fiche# OTS0532110  |
| 2,4-Dinitroaniline          | 97-02-9  | HEGTOXCHRM<br>Mammalian bone marrow micronucleus assay          | Non-TSCA Protocol/Guideline (see docket #OPTS-42054B) | mice                                     | oral (gavage), single dose                    | 0, 37.5, 75, 150 mg/kg body weight      | 5/sex             | Test animals treated with 2,4-dinitroaniline had an incidence of micronucleated polychromatic erythrocytes within normal range. The ratio of polychromatic normochromatic erythrocytes in both male and female test animals remained unaffected. Results indicated that the test material was not mutagenic.      | 53 FR 45385; 11/9/88<br>Fiche# OTS0519120   |
| 2,6-Dichloro-4-nitroaniline | 99-30-9  | EEATOX<br>Algae acute toxicity                                  | Non-TSCA Protocol/Guideline (see docket #OPTS-42054B) | <i>Selenastrum capricornutum</i> (algae) | static, 96 hr                                 | 0.9, 1.3, 1.9, 2.8, 4.2 mg/L (measured) | Not applicable    | Exposure to the test material (2,6-dichloro-4-nitroaniline) resulted in a 96-hour EC <sub>50</sub> value of 2.6 mg/L. The no-observed-effect concentration was 0.9 mg/L.  | 54 FR 25167; 6/13/89<br>Fiche# OTS0519117   |
| 2,6-Dichloro-4-nitroaniline | 99-30-9  | EEATOX<br>Acute invertebrate toxicity                           | Non-TSCA Protocol/Guideline (see docket #OPTS-42054B) | <i>Daphnia magna</i>                     | flow-through, 48 hr                           | 0.86-5.0 mg/L (nominal)                 | 20 (10/replicate) | Exposure to 2,6-dichloro-4-nitroaniline produced a 48-hour EC <sub>50</sub> value greater than 4.4 mg/L (the highest concentration due to solubility limitations). No evidence of acute toxicity was seen at any test concentration.  | 54 FR 25167; 6/13/89<br>Fiche# OTS0519117   |
| 2,6-Dichloro-4-nitroaniline | 99-30-9  | EECLIF<br>Fish early life stage test                            | Non-TSCA Protocol/Guideline (see docket #OPTS-4453B)  | rainbow trout                            | flow-through, 91 d                            | 0.011-0.19 mg/L                         | 60/ concentration | Decreased larval survival was noted at 0.024 mg/L and higher. The NOEC was 0.011 mg/L and the MATC was 0.016 mg/L.  | 54 FR 30605; 8/31/89,<br>Docket# OPTS-44536 |
| Cyclohexanone               | 108-94-1 | HEGTOXCHRM<br>Mammalian cytogenetics assay                      | Non-TSCA Protocol/Guideline (see docket # OPTS-42046) | Chinese hamster ovary (CHO)              | <i>in vitro</i> , 1 hr                        | 2.5, 5.0, 7.5, 10.0, 12.5 µL/mL         | Not applicable    | The test material did not induce significant increases in chromosomal aberrations with or without S9 activation.  | 49 FR 44142; 11/2/84,<br>Fiche# OTS0507477  |
| Cyclohexanone               | 108-94-1 | HEGTOXDNAF<br>Sister chromatid exchange                         | Non-TSCA Protocol/Guideline (see docket # OPTS-42046) | Chinese hamster ovary (CHO)              | <i>in vitro</i> , 1 hr                        | 2.5, 5.0, 7.5, 10.0, 12.5 µL/mL         | Not applicable    | When treated without S9 metabolic activation, increases in SCE (sister chromatid exchange) frequency were seen at the higher concentrations. The test material with S9 metabolic activation did not induce SCEs.  | 49 FR 44142; 11/2/84,<br>Fiche# OTS0507477  |
| Cyclohexanone               | 108-94-1 | HEGTOXMUTA<br>Sex-linked recessive lethal test (voluntary test) | Non-TSCA Protocol/Guideline (see docket # OPTS-42046) | <i>Drosophila melanogaster</i>           | inhalation, 4 hr                              | 1900 ppm (36% saturation)               | Not specified     | No evidence of treatment-induced increased sex-linked recessive lethals was seen.   | 52 FR 2152; 1/20/87,<br>Fiche# OTS0511205   |
| Cyclohexanone               | 108-94-1 | HEGTOXMUTA<br>Gene mutation (CHO/HPRT)                          | Non-TSCA Protocol/Guideline (see docket # OPTS-42046) | Chinese hamster ovary (CHO)              | <i>in vitro</i> , 1 hr                        | 2.5, 5.0, 7.5, 10.0, 12.5 µL/mL         | Not applicable    | Cytotoxicity occurred at a concentration of 12.5 µL/mL. No evidence of increased mutations at the HPRT locus was seen in any of these assays, with or without S9 activation.  | 49 FR 44142; 11/2/84,<br>Fiche# OTS0507477  |
| Cyclohexanone               | 108-94-1 | HERTOXTERA<br>Developmental study                               | Non-TSCA Protocol/Guideline (see docket # OPTS-42046) | mice                                     | inhalation, 6 h/d, gestation days 6-17        | 0, 1400 ppm (nominal)                   | 30 mated females  | Maternal toxicity occurred in treated mice (decreased mean body weight, weight gain, mean uterine weight, uterine implantation, and number of viable fetuses per pregnant animal). Fetuses showed decreased body weights. No treatment-related effects were noted on external, skeletal, or visceral development. | 49 FR 44142; 11/2/84,<br>Fiche# OTS0507478  |

## Results of Testing

| Chemical Name                   | CAS No.   | Study Code/Type  | Protocol/Guideline  | Species         | Exposure                                      | Dose/Concentration                                   | No. per Group                           | Results  | Reference                               |
|---------------------------------|-----------|--|---|-----------------|---|--|---|--|---|
| Cyclohexanone                   | 108-94-1  | HERTOXTERA<br>Developmental toxicity                         | Non-TSCA Protocol/<br>Guideline (see docket # OPTS-42046) | rats            | inhalation, 6 hr/d, gestation days 6-19       | 0, 300, 650, 1400 ppm (nominal)                      | 26 mated females                        | Maternal toxicity was evident in the high-dose group (decreased body weight and weight gain). No evidence of reproductive toxicity was noted. Fetuses from the high dose groups also exhibited decreased body weights. At the high-dose, the incidence of fetuses with at least one ossification variation was increased.  | 49 FR 44142; 11/2/84, Fiche# OTS0507478 |
| Cyclohexanone                   | 108-94-1  | HERTOXTERE<br>Male reproductive performance (voluntary test) | Non-TSCA Protocol/<br>Guideline (see docket # OPTS-42046) | rats            | inhalation, 6 hr/d, 5 d/wk, for 2 generations | 0, 250, 500, 1000 ppm (nominal)                      | 30/sex /generation /concentration group | High-concentration F1 males showed decreased survival, body weight, and fertility, and F2 progeny also had decreased survival rates and body weights. High-concentration F1 males were rested for 2 days following the last exposure, then mated to determine whether effects were reversible. In this re-test, the results showed fertility was comparable to controls.   | 52 FR 21252; 1/20/87, Fiche# OTS0511208 |
| Cyclohexanone                   | 108-94-1  | HERTOXTERE<br>2-generation reproduction study                | Non-TSCA Protocol/<br>Guideline (see docket # OPTS-42046) | rats            | inhalation, 6 hr/d, 5 d/wk; 33 wk             | 0, 250, 500, 1000, 1400 ppm (nominal)                | 30/sex/dose                             | F0 test animals were exposed to 0, 250, 500, or 1,000 ppm during the first generation (F0). The F1 generation animals were exposed to 0, 250, 500, or 1,400 ppm of the test material. High-dose F0 animals showed transient effects for the first 2 exposure days (clinical signs such as ataxia, lacrimation, and irregular breathing); no effects were seen on body weight. F1 generation body weight was reduced in 1,400 ppm males. No effects were noted on reproductive indices.   | 51 FR 27598; 8/1/86, Fiche# OTS0511206  |
| Bis(2-ethylhexyl)-terephthalate | 6422-86-2 | EEATOX<br>Acute fish toxicity                                | Non-TSCA Protocol/<br>Guideline (see docket #OPTS-42039)  | Rainbow trout   | 96 hr, flow-through                           | 0.022, 0.045, 0.090, 0.18, 0.35 mg/L (nominal)       | Not specified                           | Neither mortality nor abnormal effects were observed. The 7-day observed No-Effect-Level of the test material was the highest mean measured test concentration, 0.25 mg/L.   | 50 FR 1892; 5/3/85, Fiche# OTS0507302   |
| Bis(2-ethylhexyl)-terephthalate | 6422-86-2 | EEBIOC<br>Mollusk Bioconcentration study                     | Non-TSCA Protocol/<br>Guideline (see docket #OPTS-42039)) | Eastern oysters | 38 day, salt water                            | 50 µg/L (nominal)                                    | Not specified                           | The aqueous <sup>14</sup> C-residue concentrations remained relatively constant throughout the exposure period. The mean concentration of 48.4 ± 7.56 µg/L represents 97% of the nominal concentration of 50 µg/L. The maximum bioconcentration factor of the <sup>14</sup> C-labeled test material was 790. The maximum concentration in the test animals was observed on day 3 of the exposure period. Analysis indicated that 79.4-80.7% of the accumulated <sup>14</sup> C-residue the test material, and 19.3-20.6% were metabolites and/or degradation products. | 52 FR 2152; 1/20/87, Fiche# OTS0510738  |
| Bis(2-ethylhexyl)-terephthalate | 6422-86-2 | EECLIF<br>Fish early life stage                              | Non-TSCA Protocol/<br>Guideline (see docket #OPTS-42039)  | Rainbow trout   | 60 day, flow-through                          | 0.014, 0.024, 0.047, 0.15, 0.28 mg/L (mean measured) | Not specified                           | No effects were noted on hatchability, survival of fry, or growth as measured by length or weight at the limit of solubility. The maximum acceptable toxicant concentration was 0.28 mg/L (measured) at 25 °C.   | 51 FR 16203; 5/01/86, OPTS0510733       |
| Bis(2-ethylhexyl)-terephthalate | 6422-86-2 | EEOTHR<br>Oyster shell deposition test                       | Non-TSCA Protocol/<br>Guideline (see docket #OPTS-42039)  | Eastern oysters | 96 hr, flow-through                           | 31.2, 62.5, 125, 250, 500 µg/L (nominal)             | Not specified                           | The estimated 96-hr EC <sub>50</sub> value for the test material measured was >624 µg/L, the highest concentration tested. Reduced shell deposition was observed in the solvent controls which received 0.50 mL of acetone per liter of seawater, a concentration of solvent equal to that delivered at the high concentration of the test material. No reduction in shell deposition was attributed to the test material.   | 52 FR 2152; 1/20/87, Fiche# OTS0510737  |

## Results of Testing

| Chemical Name                   | CAS No.   | Study Code/Type                             | Protocol/Guideline                                       | Species                         | Exposure   | Dose/Concentration                      | No. per Group  | Results   | Reference                                |
|---------------------------------|-----------|---|--|---------------------------------|--|---|----------------|---|--|
| Bis(2-ethylhexyl)-terephthalate | 6422-86-2 | EESEED<br>Seed germination study            | Non-TSCA Protocol/<br>Guideline (see docket #OPTS-42039) | radish, ryegrass, soybean seeds | 16 hr light/8 hr dark photoperiod, 14 day  | 0.15, 1.5, 15, 150, 1500 µg/L (nominal) | Not specified  | The EC <sub>50</sub> value was estimated to be greater than 1400 µg/L (measured) for radish and ryegrass seeds. For soybean seeds, the EC <sub>50</sub> value was estimated to be greater than 1500 µg/L (measured). No toxic trend was apparent.   | 51 FR 27598; 8/1/86, Fiche# OTS0510736   |
| Bis(2-ethylhexyl)-terephthalate | 6422-86-2 | EFBDEG<br>Biodegradation study              | Non-TSCA Protocol/<br>Guideline (see docket #OPTS-42039) | Not applicable                  | 28 day, shake flask using carbon-free deionized water.                                   | 1 mg/L carbon equivalent                | Not applicable | Gas chromatographic measurement of the test material remaining in the flasks at the end of the radiolabeled study indicated that 56% of the original test material was degraded in 28 days. Radioanalysis found 40.2% of the original activity present in the KOH trappings. It is suggested that the test material was susceptible to both ultimate and primary degradation with an environmental half-life of >28 days for ultimate degradation and <28 days for primary degradation.   | 50 FR 1892; 5/3/85, Fiche# OTS0510731    |
| Bis(2-ethylhexyl)-terephthalate | 6422-86-2 | EFPCHEPART<br>Octanol/water coefficient     | Non-TSCA Protocol/<br>Guideline (see docket #OPTS-42039) | Not applicable                  | Shake flask, well water and sea water  | 1% and 0.1% (v/v)                       | Not applicable | The octanol/water partition coefficient (P) of the test compound, was determined through shake-flask batch extraction and gas-liquid chromatography. A mean P value for well water was determined to be $5.2 \times 10^3$ , with a relative standard deviation of 60%. The sea water mean P value was found to be $1.8 \times 10^3$ with a relative standard deviation of 19%.  | 50 FR 1892; 5/3/85, Fiche# OTS0507302    |
| Bis(2-ethylhexyl)-terephthalate | 6422-86-2 | EFPCHEWSOL<br>Water solubility              | Non-TSCA Protocol/<br>Guideline (see docket #OPTS-42039) | Not applicable                  | 72 hr in environmental chamber at 25 °C using deionized water, well water, or sea water. | Not applicable                          | Not applicable | The mean solubilities of the test material in sea water, well water, and deionized water were $6.1 \pm 0.2 \times 10^2$ ppb, $3.5 \pm 0.1 \times 10^2$ ppb, and $15 \pm 0.6 \times 10^2$ ppb, respectively.   | 50 FR 1892; 5/3/85, Fiche# OTS0507301    |
| Bis(2-ethylhexyl)-terephthalate | 6422-86-2 | HEADME<br>Pharmacokinetics (Voluntary test) | Non-TSCA Protocol/<br>Guideline (see docket #OPTS-42039) | rats                            | Gavage, single dose  | 100 mg/kg/body wt.                      | 10 males       | About 63% of the administered dose was rapidly hydrolyzed to 2-ethylhexanol (2-EH), mono-(2-ethylhexyl)terephthalate (MEHT), and unlabeled terephthalic acid (TPA). The remainder of the dose was excreted unchanged in the feces. Recovery of the administered dose was as follows: in the urine ( $31.9\% \pm 10.9\%$ ) and in expired air as $^{14}\text{CO}_2$ ( $3.6\% \pm 0.9\%$ ). Major metabolites in the urine included TPA, oxidized metabolites of 2-EH and MEHT, and glucuronic and sulfuric acid conjugates. The total recovery for the dose was $93.0 \pm 2.2\%$ . All tissues examined contained $^{14}\text{C}$ with the highest concentration in the liver and fat. Excretion of 95 and 99% of the total urinary and fecal radioactivity occurred by 24 and 48 hours. | 50 FR 5421; 2/6/85, Fiche# OTS0507299    |
| Bis(2-ethylhexyl)-terephthalate | 6422-86-2 | HEGTOXCHRM<br>Mammalian cytogenetic study   | Non-TSCA Protocol/<br>Guideline (see docket #OPTS-42039) | Chinese hamster ovary cells     | <i>in vitro</i>  | 700, 800, 1000 nL/mL                    | Not applicable | No significant increases in the frequency of chromosomal aberrations were seen at any dose level with or without metabolic activation.  | 51 FR 6468; 2/24/86, OTS0206697          |
| Bis(2-ethylhexyl)-terephthalate | 6422-86-2 | HEGTOXMUTA<br>Mutagenicity study            | Non-TSCA Protocol/<br>Guideline (see docket #OPTS-42039) | <i>Salmonella typhimurium</i>   | <i>in vitro</i>  | 0.32-1000 µg/plate                      | Not applicable | The tested strains used were TA98, TA100, TA1535, TA1537, and TA1538. The test material was not mutagenic when assayed in the presence or absence of metabolic activation.  | 50 FR 46699; 11/12/85, Fiche# OTS0510734 |

## Results of Testing

| Chemical Name                   | CAS No.   | Study Code/Type  | Protocol/Guideline   | Species                             | Exposure  | Dose/Concentration               | No. per Group              | Results  | Reference  |
|---------------------------------|-----------|--|--|-------------------------------------|---|----------------------------------|----------------------------|--|--|
| Bis(2-ethylhexyl)-terephthalate | 6422-86-2 | HEGTOXMUTA<br>Mutagenicity study                                 | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42039)  | Chinese<br>hamster ovaries<br>(CHO) | <i>in vitro</i>   | 1.25, 2.5, 10.0, 20.0<br>nL/mL   | Not applicable             | Treated non-activated cultures had cell survivals relative to the solvent control (dimethyl sulfoxide) of 82.3, 87.9, 96.7, 72.9, and 69.2% respectively. Activated cultures had cell survivals of 106.7, 106.3, 114.4, 91.7, and 99.4%, respectively. The test material did not produce mutant frequencies significantly greater than the solvent control either with or without metabolic activation.  | 51 FR 6468; 2/24/86,<br>OTS0206697               |
| Bis(2-ethylhexyl)-terephthalate | 6422-86-2 | HESTOX<br>Subchronic oral<br>toxicity                            | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42039)  | rats                                | Oral (dietary), 90 day                                    | 0, 0.1, 0.5, 1.0 %<br>(w/w)      | 17-20 males and<br>females | There were statistically significant differences in the treated groups compared to the controls in the following areas: decreased mean corpuscular hemoglobin (0.5% females, 1.0% test animals), hemoglobin (1.0% animals, 0.1% males), and hematocrit. Variations of red blood cell morphology were observed in all groups, including microcytosis, anisocytosis, poikilocytosis, and spherocytosis. No treatment-related gross or microscopic abnormalities were observed. There were no treatment-related differences in mortality, body weight gain, food consumption, clinical signs of toxicity, and absolute and relative organ weight. | 50 FR 46699;<br>11/12/85, Fiche#<br>OTS0510735   |
| Phenol                          | 108-95-2  | HEATOX<br>Respiratory toxicity                                   | Non-TSCA Protocol/<br>Guideline (see docket<br>OPPTS-42150B) | F344 rat                            | inhalation,<br>6 h/d, 5 d/wk<br>14 days, 2 wk<br>recovery | 0, 0.5, 5, 25 ppm                | 10/sex                     | Clinical pathology measurements, organ weights, gross and microscopic pathology examinations made at the end of the exposure period and after the 2-week recovery period did not indicate treatment-related effects. Microscopic evaluations conducted on the liver, kidney and respiratory tract of rats in the control and high-exposure groups at termination and recovery did not show lesions related to phenol exposure. Thus the NOEL for this study was greater than 25 ppm. [EPA]   | 63 FR 10620, 3/4/98<br>Docket# OPPTS-<br>44646   |
| Phenol                          | 108-95-2  | HENEUR<br>Motor activity,<br>subchronic                          | NTIS 91-154617   | rats                                | drinking water  | Not specified                    | Not specified              |  | due 10/98  |
| Phenol                          | 108-95-2  | HENEUR<br>Neuropathology,<br>subchronic                          | NTIS 91-154617   | rats                                | drinking water  | Not specified                    | Not specified              |  | due 10/98  |
| Phenol                          | 108-95-2  | HENEUR<br>Functional observa-<br>tional battery, sub-<br>chronic | NTIS 91-154617   | rats                                | drinking water  | Not specified                    | Not specified              |  | due 10/98  |
| Phenol                          | 108-95-2  | HERTOXTERE<br>Reproductive toxicity                              | 40 CFR 798.4700  | rats                                | drinking water  | Not specified                    | Not specified              |  | due 6/99   |
| Isophorone                      | 78-59-1   | HECTOXCARC<br>Carcinogenicity study                              | National Toxicology<br>Program (NTP)                         | F344/N rats                         | gavage, 5 d/wk, 103<br>weeks                              | 0, 250, 500 mg/kg body<br>wt/day | 50 male, 50<br>female      | Some evidence of carcinogenicity in male rats as shown by the occurrence of renal tubular cell adenomas and adenocarcinomas. No evidence of carcinogenicity in female rats.  | NTP TR-291, January<br>1986,<br>NTIS PB86-181823 |

## Results of Testing

| Chemical Name   | CAS No. | Study Code/Type  | Protocol/Guideline  | Species                       | Exposure   | Dose/Concentration                         | No. per Group                  | Results   | Reference                                     |
|-----------------|---------|--|---|-------------------------------|--|--|--------------------------------|---|---|
| Isophorone      | 78-59-1 | HECTOXCARC<br>Carcinogenicity study                            | NTP   | B63F <sub>1</sub> mice        | gavage, 5 d/wk, 103 weeks  | 0, 250, 500 mg/kg body wt/day              | 50 male, 50 female             | Equivocal evidence of carcinogenicity in male mice as shown by an increased occurrence of hepatocellular adenomas and carcinomas (combined) and of mesenchymal tumors in the integumentary system in animals given 500 mg/kg/d and an increase in malignant lymphomas in animals given 250 mg/kg/d.. No evidence of carcinogenicity in female mice. | NTP TR-291, January 1986,<br>NTIS PB86-181823 |
| Isophorone      | 78-59-1 | HEGTOXCHRM<br>Cytogenetic assay                                | Non-TSCA Protocol/<br>Guideline (see docket #42029)       | mice                          | intraperitoneal, single injection                                  | 0.54 mL/kg                                 | 10 (5 male, 5 female)          | The incidence of micronucleated polychromatic erythrocytes and the ratio of normochromatic to polychromatic erythrocytes were not significantly different in the treatment groups compared with the vehicle controls.   | 50 FR 5421; 3/6/85<br>Fiche# OTS0507222       |
| Isophorone      | 78-59-1 | HEGTOXDNAF<br>Unscheduled DNA synthesis                        | Non-TSCA Protocol/<br>Guideline (see docket #42029)       | rats                          | <i>in vitro</i>  | 0.40, 0.20, 0.10, 0.50, 0.01, 0.0005 µL/mL | Not applicable                 | None of the tested concentrations caused a significant increase in unscheduled DNA synthesis in primary hepatocytes over the solvent (ethanol) control.   | 50 FR 5421; 3/6/85<br>Fiche# OTS0507222       |
| Isophorone      | 78-59-1 | HEGTOXMUTA<br>Mutagenicity study                               | Non-TSCA Protocol/<br>Guideline (see docket #42029)       | mouse                         | <i>in vitro</i>  | 0.067-1.3 µL/mL                            | Not applicable                 | L5178YTK cell viability ranged from 12-111% in the non-activated and 9-86% of control in the S9-activated cultures. None of the cultures produced mutation frequencies which were significantly greater than the controls.  | 50 FR 5421; 3/6/85<br>Fiche# OTS0507222       |
| Isophorone      | 78-59-1 | HERTOXTERA<br>Developmental toxicity                           | Non-TSCA Protocol/<br>Guideline (see docket #42029)       | rats and mice                 | inhalation, 6 hr/d; days 6-15 of gestation                         | 0, 25, 50, 115 ppm                         | 22 rats; 22 mice (pregnant)    | Maternal toxicity was evident by differences found between dosed groups and controls for mean body weight and food consumption (115 ppm group of rats and mice). No statistically significant differences among the control and treated groups were found for any of the fetal external, visceral, or skeletal parameters.                          | 49 FR 5187; 2/10/84<br>Fiche# OTS0507224      |
| Dichloromethane | 75-09-2 | HECTOXCARC<br>Carcinogenicity                                  | National Toxicology Program (NTP)                         | F344/N rats                   | inhalation, 6 hr/d, 5 d/wk, 102 weeks                              | 0, 1000, 2000, 4000 ppm                    | 50 male, 50 female             | There was some evidence of carcinogenicity in male rats as shown by an increased incidence of benign neoplasms of the mammary gland. There was clear evidence of carcinogenicity in female rats as shown by increased incidences of benign neoplasms of the mammary gland   | NTP TR-306, January 1986                      |
| Dichloromethane | 75-09-2 | HECTOXCARC<br>Carcinogenicity                                  | NTP   | B6C3F <sub>1</sub> mice       | inhalation, 6 hr/d, 5 d/wk, 102 weeks                              | 0, 2000, 4000 ppm                          | 50 male, 50 female             | There was clear evidence of carcinogenicity in male and female mice, as shown by increased incidences of alveolar/bronchiolar neoplasms and of hepatocellular neoplasms.  | NTP TR-306, January 1986                      |
| Dichloromethane | 75-09-2 | HERTOXTERE<br>2-Generation reproduction study (voluntary test) | Non-TSCA Protocol/<br>Guideline (see docket # OPTS-42023) | rats                          | inhalation, 6 hr/d, 5 d/wk from 14 wk to age of weaning of F1 pups | 0, 0.07, 0.24, 0.7 mg/L                    | 30 male and female (F0 and F1) | Observations of the F0 and F1 animals included treatment-related decreased body weight in low-, mid-, and high-dose males, and in high-dose females. There were no treatment-related reproductive effects.  | 50 FR 1892; 5/3/85<br>OTS0206809              |
| Formamide       | 75-12-7 | HEGTOXMUTA<br>Ames test  | National Toxicology Program (NTP)                         | <i>Salmonella typhimurium</i> | <i>in vitro</i>  | Not specified                              | Not specified                  | Negative response   | NTP Results Report 8/8/96                     |
| Formamide       | 75-12-7 | HEGTOXMUTA<br>Sex-linked recessive lethal assay                | NTP   | <i>Drosophila</i>             | Not specified  | Not specified                              | Not specified                  | Negative response   | NTP Results Report 8/8/96                     |



## Results of Testing

| Chemical Name   | CAS No. | Study Code/Type   | Protocol/Guideline   | Species | Exposure  | Dose/Concentration                 | No. per Group         | Results  | Reference                                     |
|-----------------|---------|---|--|---------|---|------------------------------------|-----------------------|--|---|
| Formamide       | 75-12-7 | HESTOX<br>Range-finding study                                     | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42032)    | rats    | dermal, 1x/d; 5d/wk;<br>2wks                          | 0, 100, 300, 1000, 3000<br>mg/kg/d | 10 male,<br>5 female  | All of the treatment groups had a decrease in body weight gain. No other toxic effects were observed at any of the selected concentrations. No clinical or behavioral abnormalities were observed.   | 49 FR 5187; 2/10/84<br>Fiche# OTS0507216      |
| Formamide       | 75-12-7 | HESTOX<br>Subchronic study  | Non-TSCA Protocol/<br>Guideline see docket<br>#OPTS-42032)     | rats    | dermal occluded,<br>6hr/d; 5d/wk; 90 days             | 0, 30, 100,<br>3000 mg/kg/d        | 10 male,<br>10 female | Mortality was observed in 3 out of 20 of the high dosed male rats. Observations of high dose animals revealed erythema of the skin, dyspnea, poor general state, shaggy fur, staggering, reduced food consumption, and decreased body weight. Hematological findings revealed increases in mean hemoglobin content per erythrocyte, mean corpuscular hemoglobin concentration values, and mean cell volume. In males, there were reductions in leukocyte and lymphocyte values, and in platelet counts. Necropsy observations included decreases in absolute weight of the liver, kidneys, spleen, testes, and adrenal glands in the males. Both sexes had increases in relative weights of the liver and kidneys. | 50 FR 31919; 8/7/85<br>Fiche# OTS0521699      |
| Propylene Oxide | 75-56-9 | HENEUR<br>Neuropathology<br>(Voluntary test)                      | Non-TSCA Protocol/<br>Guideline (see docket<br>OPPTS # 42028D) | rats    | inhalation; 6 hr/d;<br>24 wks                         | 0, 30, 100, 300 ppm                | 30 males              | There was no evidence of treatment-related neurotoxicity in test animals. Decreased body weight gain was observed at all test levels. No treatment related gross or histopathologic lesions were noted.  | 51 FR 6468; 2/24/86<br>Fiche# OTS0510835      |
| Propylene Oxide | 75-56-9 | HENEUR<br>Motor activity<br>(Voluntary test)                      | Non-TSCA Protocol/<br>Guideline (see docket<br>OPPTS # 42028D) | rats    | inhalation; 6 hr/d;<br>24 wks                         | 0, 30, 100, 300 ppm                | 30 males              | No alterations in motor activity were attributable to treatment.   | 51 FR 6468; 2/24/86<br>Fiche# OTS0510835      |
| Propylene Oxide | 75-56-9 | HENEUR<br>Functional<br>observational battery<br>(Voluntary test) | Non-TSCA Protocol/<br>Guideline (see docket<br>OPPTS # 42028D) | rats    | inhalation; 6 hr/d;<br>24 wks                         | 0, 30, 100, 300 ppm                | 30 males              | No functional alterations were attributable to treatment.  | 51 FR 6468; 2/24/86<br>Fiche# OTS0510835      |
| Propylene Oxide | 75-56-9 | HERTOXTERA<br>Developmental<br>toxicity                           | 40 CFR 798.4359<br>(modified)                                  | rats    | inhalation; 6 hr/d,<br>gestation days 5<br>through 15 | 0, 100, 300, 500 ppm<br>(measured) | 25 mated<br>females   | Maternal toxicity (reduced weight gain and food consumption) occurred in high-dose animals. No exposure-related effects were noted on development. The maternal NOEL was 300 ppm and the developmental NOEL was 500 ppm.   | 53 FR 951; 1/14/88<br>Fiche# OTS0534122       |
| Propylene Oxide | 75-56-9 | HERTOXTERA<br>Developmental<br>toxicity screen                    | Non-TSCA Protocol/<br>Guideline (see docket<br>OPPTS # 42028D) | rats    | 6 hr/d, gestation days 6<br>through 15                | 0, 300, 500, 750 ppm<br>(nominal)  | 10 mated<br>females   | Maternal toxicity (reduced body weight gain and food consumption) and fetal toxicity (decreased mean number of viable fetuses and increased postimplantation loss) occurred at the high dose. Decreased maternal body weight gain was noted in the mid-dose group. Based on these results, 100, 300, and 500 ppm were selected concentrations for the definitive study.  | 52 FR 39560;<br>10/22/87<br>Fiche# OTS0534100 |
| Propylene Oxide | 75-56-9 | HERTOXTERE<br>2-Generation study<br>(Voluntary test)              | Non-TSCA Protocol/<br>Guideline (see docket<br>OPPTS # 42028D) | rats    | inhalation; 14 wks                                    | 0, 30, 100, 300 ppm                | Not specified         | Body weights were considerably decreased in both sexes at 300 ppm. Body weights were also decreased in males at 100 and 300 ppm. No significant differences in body weights were observed in F <sub>0</sub> or F <sub>1</sub> females exposed to 30 or 100 ppm. Neonatal survival and growth among F <sub>0</sub> and F <sub>1</sub> litters were not significantly different from their control groups. Fertility was unaffected by exposure.   | 50 FR 46699;<br>11/12/85<br>Fiche# OTS0510892 |

## Results of Testing

| Chemical Name | CAS No. | Study Code/Type  | Protocol/Guideline  | Species  | Exposure   | Dose/Concentration   | No. per Group  | Results   | Reference                                      |
|---------------|---------|--|---|--|--|--|----------------|---|--|
| Biphenyl      | 92-52-4 | EEATOX<br>Acute fish toxicity<br>(Voluntary test)            | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42031) | Rainbow trout  | 96 hr, static and 192<br>hr, flow-through  | Not reported   | Not specified  | 96-hour static LC <sub>50</sub> > 0.81 mg/L<br>192-hour flow-through LC <sub>50</sub> = 1.3 (0.81 to 1.5) mg/L<br>Lowest effect concentration (not eating) >0.6 mg/L  | 52 FR 39560;<br>10/22/87, Fiche#<br>OTS0528241 |
| Biphenyl      | 92-52-4 | EEBIOC<br>Mollusk biocon-<br>centration                      | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42031) | <i>Crassostrea<br/>virginica</i><br>(eastern oyster) | 28 d, flow-through,<br>seawater  | 0.058 ± 0.002 mg/L<br>(mean, measured)                               | Not specified  | Uptake by tissues was rapid; equilibrium was reached at 7<br>days. The BCF of parent biphenyl at day 28 was 110. The<br>mean tissue concentration was 102 mg/kg total biphenyl<br>equivalents. Less than 1% of C-14 activity was associated<br>with hydroxybiphenyl metabolites.  | 54 FR 12953; 3/29/89,<br>Fiche# OTS0528276     |
| Biphenyl      | 92-52-4 | EECLIF<br>Fish early life stage                              | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42031) | <i>Salmo<br/>gairdneri</i><br>(rainbow trout)        | 87 days, flow-through  | 0.063, 0.099, 0.143,<br>0.229, 0.332, 0.564<br>mg/L (mean, measured) | Not specified  | The no-effect concentration was 0.229 mg/L and lowest-<br>effect concentration was 0.332 mg/L (weight), yielding the<br>maximum acceptable toxicant concentration (MATC) at<br>0.275 mg/L (geometric mean).   | 53 FR 17760; 5/18/88,<br>Fiche# OTS0528268     |
| Biphenyl      | 92-52-4 | EEOTHR<br>Oyster shell deposition<br>test                    | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42031) | <i>Crassostrea<br/>virginica</i><br>(eastern oyster) | 96 hr, flow-through  | 0.024 to 0.269 mg/L<br>(mean, measured)                              | Not specified  | New shell was not reduced by 50% in any test treatments as<br>compared to controls; EC <sub>50</sub> (shell growth) was therefore<br>>0.269 mg/L.   | 54 FR 1229; 1/12/89,<br>Fiche# OTS0528249      |
| Biphenyl      | 92-52-4 | EFBDEG<br>Anaerobic aquatic<br>biodegradation                | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42031) | Not applicable                                       | 4, 8, and 12 weeks,<br>sewage lagoon<br>sediment. Anaerobic,<br>denitrifying and<br>methanogenic<br>conditions | 0.98 mg/L (nominal)  | Not applicable | No evidence of significant anaerobic biodegradation was<br>seen under either denitrifying or methanogenic processes.<br>Volatilization was not a significant factor because of limited<br>sparging and the sediment's holding power. Mean C-14<br>activity in the porous polymer trap of 12-week ecocores was<br>4.0% of dose.  | 53 FR 43267;<br>10/26/88, Fiche#<br>OTS0528274 |
| Biphenyl      | 92-52-4 | EFBDEG<br>Aerobic aquatic<br>biodegradation                  | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42031) | Not applicable                                       | Shake-flask, 11 days,<br>river sediment,<br>aerobic  | 77 µg/L, 1 mg/L  | Not applicable | Mineralization to CO <sub>2</sub> accounted for about 40% of C-14<br>activity at both concentrations; after 10 days, the mean level<br>of C-14 in the sediment was 9% of test levels.   | 53 FR 23459; 6/22/88,<br>Fiche# OTS0528271     |
| Biphenyl      | 92-52-4 | EFBDEG<br>Aerobic aquatic<br>biodegradation                  | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42031) | Not applicable                                       | Shake-flask, 10 days,<br>lake sediment/water<br>system, aerated  | 77 µg/L, 1 mg/L  | Not applicable | Mineralization to CO <sub>2</sub> ranged from 6 to 36% at the high<br>dose, and 32 to 43% at the low dose. Mean mass balance in<br>active microcosms was 88.0%, compared to 77.3% for sterile<br>microcosms. Data indicate biphenyl biodegrades aerobically,<br>and the half-life in lake sediment from Busch Wildlife<br>Reserve was estimated to be 6 to 10 days, compared to 2 to 3<br>days in Illinois River water. | 53 FR 28909; 8/1/88,<br>Fiche# OTS0528273      |
| Bisphenol A   | 80-05-7 | EEATOX<br>Acute fish toxicity<br>(Voluntary test)            | Non-TSCA Protocol/<br>Guideline                             | Atlantic<br>silverside                               | 96 hr, flow-through  | 5.4, 8.2, 13.0, 20.0, 30.0<br>mg/L (nominal)                         | Not specified  | The 96-hour LC <sub>50</sub> value was 9.4 mg/L with its corresponding<br>95% confidence interval between 8.3-11.0 mg/L.  | 50 FR 46699;<br>11/12/85, Fiche#<br>OTS0510008 |
| Bisphenol A   | 80-05-7 | EEATOX<br>Mysid shrimp acute<br>toxicity<br>(Voluntary test) | 40 CFR 797.1930   | Mysid shrimp   | 96 hr, flow-through  | 0.51, 0.86, 1.4, 1.9, 3.3<br>mg/L (nominal)                          | Not specified  | The 96-hour LC <sub>50</sub> value was calculated to be 1.1 mg/l with a<br>corresponding 95% confidence interval between 0.92 and 1.2<br>mg/L. After 96 hours, one mortality was observed in the<br>control group. Mortality of 20% was observed at a<br>concentration of 0.86 mg/L in the exposed population.  | 50 FR 46699;<br>11/12/85,<br>Fiche# OTS0510008 |

## Results of Testing

| Chemical Name | CAS No. | Study Code/Type  | Protocol/Guideline                | Species                 | Exposure                | Dose/Concentration                                      | No. per Group  | Results  | Reference                                  |
|---------------|---------|--|-----------------------------------|-------------------------|-------------------------|---|--|--|--|
| Bisphenol A   | 80-05-7 | EEATOX<br>Acute fish toxicity<br>(Voluntary test)            | 40 CFR 797.1400                   | Fathead minnows         | 96 hr, flow-through     | 1.00, 1.54, 2.37, 3.65, 5.62, 8.65 mg/L (nominal)       | Not specified  | The 96-hour LC <sub>50</sub> and 95% confidence interval values were 4.7 and 3.6-5.4 mg/L respectively. At the 3.58 mg/L exposure level, 9 out of the 10 test animals experienced loss of equilibrium at the 24 hour mark. The test animals however, continued to recover throughout the remainder of the test and appeared normal at the end of the study.  | 50 FR 46699; 11/12/85, Fiche# OTS0510594   |
| Bisphenol A   | 80-05-7 | EEATOX<br>Acute invertebrate toxicity<br>(Voluntary test)    | 40 CFR 797.1300                   | <i>Daphnid magna</i>    | 48 hr, static           | 0.93, 1.55, 2.60, 4.32, 7.20, 12.0, 20.0 mg/L (nominal) | Not specified  | The EC <sub>50</sub> value and 95% confidence interval were 10.2 mg/L and 9.2-11.4 mg/L respectively. There was no significant toxic effect at or below analyzed test concentration of 6.97 mg/L.  | 50 FR 46699; 11/12/85, Fiche# OTS0510594   |
| Bisphenol A   | 80-05-7 | EEATOX<br>Algae acute toxicity<br>(Voluntary test)           | 40 CFR 797.1050                   | green algae             | 96 hr, static           | 0.78, 1.30, 2.16, 3.6, 6.0, 10.0 mg/L (nominal)         | Not applicable   | Algal growth was inhibited at concentrations of 1.99 mg/L and higher. The EC <sub>50</sub> values were based on 50% inhibition of cell count and total cell volume compared to the controls. The 96-hour EC <sub>50</sub> values were 2.73 and 3.10 mg/L.  | 50 FR 46699; 11/12/85, Fiche# OTS0510594   |
| Bisphenol A   | 80-05-7 | HECTOXCARC<br>Carcinogenicity study                          | National Toxicology Program (NTP) | F344 rats               | Diet, 103 weeks         | 1000 and 2000 ppm,                                      | 50 male, 50 female at each concentration.                  | No convincing evidence of carcinogenicity. Mean body weight of all groups of rats were lower than controls, probably due to lower food consumption. Leukemias occurred at increased incidence in both sexes, but the increase was marginally significant in males and not statistically significant in females. A statistically significant increase in interstitial-cell tumors of the testes in male rats was suggestive of but was not considered convincing evidence of a compound-related effect because this lesion normally occurs in high incidence in aging F344 rats.  | NTP TR-215, March 1982<br>NTIS PB82-184060 |
| Bisphenol A   | 80-05-7 | HECTOXCARC<br>Carcinogenicity study                          | NTP                               | B6C3F <sub>1</sub> mice | Diet, 103 weeks         | 1000, 5000, 10,000 ppm                                  | 50 male/ 1000 or 5000 ppm<br>50 female/ 5000 or 10,000 ppm | No convincing evidence of carcinogenicity. In male mice, there was an increased incidence of leukemias or lymphomas, but this was not statistically significant. There was a compound-related increase in incidence of multinucleated giant hepatocytes in male mice, but there were no increase of liver tumors.  | NTP TR-215, March 1982<br>NTIS PB82-184060 |
| Bisphenol A   | 80-05-7 | HESTOX<br>Subchronic inhalation toxicity<br>(Voluntary test) | 40 CFR 798.2450 (modified)        | rats                    | Inhalation 6 hr/d, 2 wk | 0, 10.0, 50.0, 150 mg/m <sup>3</sup>                    | 20/sex   | No mortalities were observed at any concentration level. Clinical observations include a porphyrin like material around the nose of males exposed to 50 or 150 mg/m <sup>3</sup> . Perineal soiling was observed in females exposed to 150 mg/m <sup>3</sup> . Males exposed to 150 mg/m <sup>3</sup> had statistically significant decreases in body weight gain which returned to normal limits within one week following exposure. Histological observations included minor inflammation of the epithelial lining of the nasal cavity in males exposed to 150 mg/m <sup>3</sup> , and in females exposed to 50 or 150 mg/m <sup>3</sup> . Very slight hyperplasia of squamous epithelium in the nasal cavity were observed in males and females exposed to 50 or 150 mg/m <sup>3</sup> . All treatment related changes were reversible within the 29-day recovery period. | 50 FR 46699; 11/12/85, Fiche# OTS0510594   |

## Results of Testing

| Chemical Name                 | CAS No.  | Study Code/Type                               | Protocol/Guideline                                   | Species                                      | Exposure  | Dose/Concentration                                   | No. per Group     | Results  | Reference                                |
|-------------------------------|----------|---|--|--|---|--|-------------------|--|--|
| Bisphenol A                   | 80-05-7  | HESTOX<br>Subchronic inhalation toxicity      | 40 CFR 798.2450 (modified)                           | rats   | 6 hr/d; 5 d/wk; 13 weeks, inhalation, whole-body exposure | 0, 10, 50, 150 mg/m <sup>3</sup>                     | 30/sex            | No mortalities were seen at any level. Decreased body weight gain and perineal soiling from urine and porphyrin-like material around the nose and eyes were noted at all concentrations. Except for decreased body weight of high-dose males, all effects disappeared shortly after cessation of exposure. Transient epithelial hyperplasia and chronic inflammation of nasal submucosa were seen in mid- and high-dose animals.                               | 53 FR 13319; 4/22/88, Fiche# OTS0531639  |
| 3,4-Dichlorobenzo-trifluoride | 328-84-7 | EEATOX<br>Acute fish toxicity                 | 40 CFR 797.1400                                      | Rainbow trout                                | 96 hr, flow-through                                       | 0.34, 0.52, 0.83, 1.4, 3.4 mg/L (mean, measured)     | 20 (10/replicate) | 100% mortality was noted at the high-concentration; the no-observed effect concentration was 0.52 mg/L. The 96-hour LC <sub>50</sub> was 1.9 (1.4-3.4) mg/L.   | 53 FR 28909; 8/1/88, Fiche# OTS0526811   |
| 3,4-Dichlorobenzo-trifluoride | 328-84-7 | EEATOX<br>Acute fish toxicity                 | 40 CFR 797.1400                                      | Fathead minnow                               | 96 hr, flow-through                                       | 0.60, 0.90, 1.5, 2.2, 3.5 mg/L (mean, measured)      | 20 (10/replicate) | 100% mortality was noted at the high-concentration; the no-observed effect concentration was <0.60 mg/L. The 96-hour LC <sub>50</sub> was 2.3 (2.1-2.6) mg/L.  | 53 FR 28909; 8/1/88, Fiche# OTS0526811   |
| 3,4-Dichlorobenzo-trifluoride | 328-84-7 | EEATOX<br>Acute algae toxicity                | 40 CFR 797.1050                                      | green alga, <i>Selenastrum capricornutum</i> | 96 hr, Static, constant illumination                      | 0.40, 0.62, 1.8, 3.7, 8.6 mg/L (mean, measured)      | Not applicable    | Cell density was not reduced at any concentration.   | Fiche# OTS0526810                        |
| 3,4-Dichlorobenzo-trifluoride | 328-84-7 | EEATOX<br>Acute invertebrate toxicity         | 40 CFR 797.1300                                      | gammarid                                     | 96 hr, flow-through                                       | 0.52, 0.83, 1.3, 1.9, 2.8 mg/L (mean, measured)      | 20 (10/replicate) | 100% mortality was noted in the high-concentration group; the no-observed effect concentration was 1.3 mg/L. The 96-hour LC <sub>50</sub> was 1.7 (1.3-2.8) mg/L.  | 53 FR 43267; 10/26/88, OTS526812         |
| 3,4-Dichlorobenzo-trifluoride | 328-84-7 | EECLIF<br>Fish early life stage toxicity      | 40 CFR 797.1600                                      | Rainbow trout                                | 89 days (60 days post-hatch), flow-through                | 0.034, 0.068, 0.13, 0.25, 0.51 mg/L (mean, measured) | Not specified     | No effects were noted on mean embryo viability, survival, or hatchability. No effects were seen on larval survival or mean wet weight. Larval length was decreased at 0.25 mg/L and higher, and larval weight was reduced at the high concentration. The Maximum Acceptable Toxicant Concentration (MATC) was >0.13 and <0.25 mg/L (geometric mean MATC = 0.18 mg/L).  | 53 FR 51134; 12/20/88, Fiche# OTS0526813 |
| 3,4-Dichlorobenzo-trifluoride | 328-84-7 | EFBDEG<br>Ready biodegradation; closed bottle | Non-TSCA Protocol/Guideline (see docket #OPTS-42089) | Soil micro-organisms                         | 28 days, closed bottle. incubation at 20 ± 1 °C in dark   | 2, 5 mg/L  | Not applicable    | DCBTF concentrations throughout the study ranged from 0.15-0.18 mg/L and 0.31-0.39 mg/L for the 2 and 5 mg/L nominal concentrations, respectively. Degradation was not observed under these conditions.  | Fiche# OTS0526810                        |
| 1,3-Dioxolane                 | 646-06-0 | HECTOX<br>Chronic Toxicity - Study Audit      | Non-TSCA Protocol/Guideline                          | rats   | oral (drinking water), <i>ad libitum</i> , 2 years        | 0, 0.03, 0.1%  | Not specified     | The audit concluded that the study contains accurate toxicological information concerning the effects of dioxolane administered to the drinking water of male and female rats. The study had concluded that there were no statistically-significant treatment-related effects in body weight or food and water consumption. A slight reduction in testicular weights and an increase in spleen weights in treated male rats was not statistically-significant. | 51 FR 6468; 2/24/86                      |
| 1,3-Dioxolane                 | 646-06-0 | HEGTOXCHRM<br>Chromosomal aberrations         | Non-TSCA Protocol/Guideline (see docket #OPTS-42041) | Chinese hamster ovary (CHO)                  | <i>in vitro</i>   | 0, 2.0, 3.0, 4.0, 5.0 mg/mL                          | Not specified     | There was no toxicity observed at the highest dose level in either the nonactivated or activated cultures. No evidence of increased frequency of chromosome aberrations was noted in either the nonactivated or activated systems compared to the negative controls.   | 50 FR 31919; 8/7/85, Fiche# OTS0511019   |

## Results of Testing

| Chemical Name | CAS No.  | Study Code/Type  | Protocol/Guideline   | Species     | Exposure  | Dose/Concentration   | No. per Group        | Results  | Reference  |
|---------------|----------|--|--|-------------|---|--|----------------------|--|--|
| 1,3-Dioxolane | 646-06-0 | HEGTOXMUTA<br>Mutagenicity study                           | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42041)                                  | mouse       | <i>in vitro</i>   | 750-5000 nL/mL   | Not applicable       | L5178YTK cell viability ranged from 85-61% in non-activated cultures and 77.8-95.1% in the S9-activated cultures relative to controls. None of the cultures had mutation frequencies significantly greater than the solvent control (water).   | 50 FR 31919; 8/7/85,<br>Fiche# OTS0511019        |
| 1,3-Dioxolane | 646-06-0 | HEGTOXTRFM<br>Cell transformation study                    | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42041)                                  | mouse       | <i>in vitro</i>   | 1000-5000 nL/mL  | Not applicable       | There was no significant increase in the appearance of transformed foci in Balb/C-3T3 cells over the test concentration range.   | FR 50 FR31919;<br>8/7/85, Fiche#<br>OTS0511019   |
| 1,3-Dioxolane | 646-06-0 | HESTOX<br>Subchronic study                                 | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42041)                                  | rat         | oral (drinking water),<br>4 wks   | 0, 0.5, 1, 2% (v/v)  | 5 male;<br>5 female  | In the 2% treated groups (both males and females) and the 1% treated males, there were statistically significant decreases in body weight gain relative to the controls.   | 51 FR 6468; 2/24/86,<br>Fiche# OTS0510995        |
| Hydroquinone  | 123-31-9 | HEADME<br>Blood elimination kinetic study (voluntary test) | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42048D)                                 | rats        | oral (gavage), single dose  | 50 mg/kg   | 3 males              | More than 80% of the radioactivity was excreted by 8 hours post-dosing. Analysis of blood samples showed an average blood absorption rate constant of 1.3 minutes and a T <sub>max</sub> for radioactivity in the blood of 6.5 to 7.5 minutes.   | 51 FR 16203; 5/1/86,<br>Fiche# OTS0518013        |
| Hydroquinone  | 123-31-9 | HEADME<br>Dermal study (voluntary test)                    | Non-TSCA Protocol/<br>Guideline (see Feldman and Mailbach 1969; Derma-toxicology, Chapter 5) | Beagle dogs | dermal and intra-venous; 1 hr (dermal), single dose (i.v.)                                    | 4.5 g/L, 15 ml (dermal); 1 or 10 mg/kg/body wt. (i.v.)           | 8 males              | After occluded dermal application, no radioactivity of the test material was detected in the blood. Urinary excretion accounted for only 0.3% and 0.4% of the applied dose at 2 and 5 days, respectively. In the i.v. application, at 1 mg/kg, 34.5% of the dose was recovered in the urine in 7 days and 7.5% was recovered in the feces in 4 days. For the 10 mg/kg dose, recovery of the dose was 65.7% in urine and 6.1% in the feces.   | 51 FR 6468; 2/24/86,<br>Fiche# OTS0516696        |
| Hydroquinone  | 123-31-9 | HEADME<br>Metabolic study (voluntary test)                 | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42048D)                                 | rats        | intratracheal instillation, single dose   | 5, 25, 50 mg/kg/body wt.   | 5 males              | The test material was rapidly absorbed through the respiratory tract and rapidly excreted in urine and feces. Within 8 hours, ≥80.74% of the administered dose was excreted in urine. At 48 hours, ≥93.86% of the dose was excreted in the urine, feces, and expired air. Urinary conjugates were the major metabolites of the test material. Hydroquinone glucuronide accounted for 48.76 to 67.21% of the dose, and hydroquinone sulfate accounted for 19.00 to 22.07% of the administered dose. Unchanged test material was present in small quantities of approximately 2.00 to 2.85% of the dose. | 51 FR 6468; 2/24/86,<br>Fiche# OTS0518013        |
| Hydroquinone  | 123-31-9 | HEADME<br>Pharmacokinetic study (voluntary test)           | 40 CFR 795.235 (modified)  | rat         | oral (gavage), single and repeated; dermal, single dose, 1x/d; 14d (repeated), 24 hr (dermal) | 25, 350 mg/kg (single), 25 mg/kg/d (repeated), 5.4% w/v (dermal) | 8 male;<br>8 female  | At 350 mg/kg, rats showed tremors, chewing, and reduced activity. No adverse effects or unusual behaviors were noted at 25 mg/kg. In the dermal study, slight to severe erythema was noted at the test site after 24 hours.  | 53 FR 28909; 8/1/88,<br>Fiche# OTS0516695        |
| Hydroquinone  | 123-31-9 | HECTOXCARC<br>Oncogenicity study                           | National Toxicology Program (NTP)  | F344/N rats | gavage, 5 d/wk, 103 wk  | 0, 25, 50 mg/kg  | 65 male<br>65 female | Some evidence of carcinogenesis in male rats as shown by marked increases in tubular cell adenomas of the kidney. Some evidence of carcinogenesis in female rats as shown by increases in mononuclear cell leukemia.   | NTP TR-366,<br>October, 1989<br>NTIS PB90-240839 |

## Results of Testing

| Chemical Name                            | CAS No.  | Study Code/Type                                       | Protocol/Guideline   | Species                  | Exposure  | Dose/Concentration      | No. per Group              | Results   | Reference   |
|--|----------|---|--|--------------------------|---|-------------------------|----------------------------|---|---|
| Hydroquinone                             | 123-31-9 | HECTOXCARC<br>Oncogenicity study                      | NTP  | B6C3F <sub>1</sub> mouse | gavage, 5 d/wk, 103 wk  | 0, 50, 100 mg/kg        | 64-65 male<br>64-65 female | No evidence of carcinogenesis in male mice administered 50 or 100 mg/kg in water. Some evidence of carcinogenesis in female mice as shown by increases in hepatocellular neoplasms, mainly adenomas. Thyroid follicular cell hyperplasia was found in male and female mice and anisolariosis, multinucleated hepatocytes, and basophilic foci of the liver in male mice.                          | NTP TR-366,<br>October, 19889<br>NTIS PB90-240839 |
| Hydroquinone                             | 123-31-9 | HENEUR<br>Neuropathology                              | 40 CFR 798.6400<br>(modified)                                | rat                      | oral (gavage), 90 d   | 0, 20, 64, 200 mg/kg/d  | Not specified              | Preliminary summary information indicates that there were no mortalities in the study. High-dose males showed tremors, reduced activity levels, and reduced body weight gain. Tremors were also seen at 64 mg/kg/day. Neuropathology analysis is in progress.   | 53 FR 47867;<br>11/28/88,<br>Fiche# OTS0516693    |
| Hydroquinone                             | 123-31-9 | HENEUR<br>Functional obser-<br>vational battery       | 40 CFR 798.6050<br>(modified)                                | rats                     | oral (gavage), 90 d   | 0, 20, 64, 200 mg/kg/d  | Not specified              | Preliminary summary information indicates that there were no mortalities in the study. High-dose males showed tremors, reduced activity levels, and reduced body weight gain. Tremors were also seen at 64 mg/kg/day. No adverse effects were seen in either sex dosed with 20 mg/kg/day. Data from the FOB is being analyzed.  | 53 FR 47867;<br>11/28/88,<br>Fiche# OTS0516693    |
| Hydroquinone                             | 123-31-9 | HERTOXTERA<br>Developmental<br>toxicity               | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42048D) | rats                     | oral (gavage),<br>gestation days 6<br>through 15                    | 0, 30, 100, 300 mg/kg/d | Not specified              | Maternal toxicity (reduced body weight gain and food intake) occurred in the high-dose dams. No effects on reproductive or developmental indices were noted in any group.   | 51 FR 6468; 2/24/86,<br>Fiche# OTS0518009         |
| Hydroquinone                             | 123-31-9 | HERTOXTERA<br>Developmental<br>toxicity               | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42048D) | rabbits                  | oral gavage, gestation<br>days 6-18                                 | 0, 25, 75, 150 mg/kg/d  | 18 mated<br>females        | Maternal toxicity (decreased body weight gain and food consumption) were noted at 75 mg/kg/day and higher. Fetotoxicity (external, visceral, and skeletal malformations and ocular defects such as microphthalmia) occurred at 150 mg/kg/day. The NOEL was 25 mg/kg/day.  | 51 FR 6468; 2/24/86,<br>Fiche# OTS0516697         |
| Hydroquinone                             | 123-31-9 | HERTOXTERE<br>2-Generation repro-<br>ductive toxicity | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42048D) | rats                     | oral (gavage), 70 days<br>prior to mating,<br>through 2 generations | 0, 15, 50, 150 mg/kg/d  | 30/sex/<br>generation      | Parental toxicity (tremors) was noted at 50 and 150 mg/kg/day. No effects were noted on any reproductive parameter in either generation at any dose level.  | 55 FR 357; 1/4/90,<br>Fiche# OTS0532768           |
| Hydroquinone                             | 123-31-9 | HESTOX<br>Subchronic study                            | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42048D) | rats                     | oral (gavage), 90 d   | 20, 64, 200 mg/kg/d     | 10 male;<br>10 female      | Rats exposed to 200 mg/kg/day showed decreased body weight gain and food consumption. Clinical observations included brown discoloration in urine at all dose levels. Behavioral changes observed included increased urination and tremors during handling. At 200 mg/kg/day, a reduction in auditory and visual orientation, forelimb strength, and responses to olfactory stimulation was seen. | 53 FR 47867;<br>11/28/88,<br>Fiche# OTS0516696    |
| Diethylene Glycol<br>Butyl Ether Acetate | 124-17-4 | HEADME<br>Pharmacokinetic study                       | 40 CFR 795.225   | rat                      | dermal, 24 hr   | 200, 2000 mg/kg (neat)  | 4/sex                      | Low-dose applications were more completely absorbed than high-dose applications. Absorption rates in high-dose rats were 1.58 mg/cm <sup>2</sup> /hour (males) and 1.28 mg/cm <sup>2</sup> /hour (females). Urinary elimination was the primary route.  | Fiche# OTS0533107                                 |

## Results of Testing

| Chemical Name                         | CAS No.    | Study Code/Type  | Protocol/Guideline         | Species                     | Exposure  | Dose/Concentration  | No. per Group | Results   | Reference                                  |
|---------------------------------------|------------|--|----------------------------|-----------------------------|---|---|---------------|---|--|
| Diethylene Glycol Butyl Ether Acetate | 124-17-4   | HEADME Pharmacokinetic study                                     | 40 CFR 795.225             | rat                         | dermal, 24 hr                                       | 200, 2000 mg/kg (neat); 200 mg/kg as a 10% (by weight) aqueous solution | 4/sex         | Low-dose applications of neat or 10% aqueous solutions were more completely absorbed than high-dose applications. Absorption rates in high-dose rats were 0.73 mg/cm <sup>2</sup> /hour (in males) and 1.46 mg/cm <sup>2</sup> /hour (in females). The primary route of elimination was via urine. Urinary metabolites included 2-(2-butoxyethoxy) acetic acid (accounting for more than 1/2 of radioactivity) and 8 to 11 additional radioactive components. | Fiche# OTS0533107                          |
| Diethylene Glycol Butyl Ether         | 112-34-5   | HEGTOX Mammalian bone marrow micronucleus assay (voluntary test) | 40 CFR 798.5395 (modified) | mouse                       | oral (gavage), single dose                          | 0, 330, 1100, 3300 mg/kg  | Not specified | DGBE did not induce a significant increase in the frequency of micronucleated bone marrow polychromatic erythrocytes compared to the control.   | 52 FR 39560; 11/22/87, Fiche# OTS0521723   |
| Diethylene Glycol Butyl Ether         | 112-34-5   | HENEUR Functional observational battery                          | 40 CFR 798.6050 (modified) | rat                         | dermal (occluded), 6 hr (single application)        | 2 mL/kg body wt.  | 4/sex         | No treatment-related effects were noted on fore- or hind-limb grip strength, hindlimb splay values, or locomotor activity.  | 54 FR 42034; 10/13/89, Fiche# OTS0521738   |
| Diethylene Glycol Butyl Ether         | 112-34-5   | HENEUR Motor activity  | 40 CFR 798.6200 (modified) | rat                         | dermal, 6 hr/d; 5 d/wk; 13 wks                      | 0, 10, 30, 100% (v/v) (a dose volume of 2 mL/kg/day)                    | 12/sex        | There were no differences in motor activity between control and treated test animals.   | 54 FR 42034; 10/13/89, Fiche# OTS0521736/8 |
| Diethylene Glycol Butyl Ether         | 112-34-5   | HENEUR Neuropathology  | 40 CFR 798.6400 (modified) | rat                         | dermal (occluded), 6 hr/d; 5 d/wk; 13 wks           | 0, 10, 30, 100% (v/v) (a dose volume of 2 mL/kg/day)                    | 12/sex        | No mortalities occurred due to treatment. Five females in the 100% DGBE dose group showed scab formation at the treatment site. Body weights and food intake were unaffected. Histopathological evaluation revealed mild degeneration of the renal tubular-epithelium in 2 males in the 100% group. There were no gross or neuropathological changes related to treatment.  | 54 FR 42034; 10/13/89, Fiche# OTS0521736/8 |
| Diethylene Glycol Butyl Ether         | 112-34-5   | HESTOX Subchronic dermal toxicity                                | 40 CFR 798.2250 (modified) | rats                        | dermal, 5 d/wk; 13 wks                              | 10, 30, 100% (a dose volume of 2 mL/kg/day)                             | 10/sex        | The high concentration produced dermal irritation in all animals, and in the low- and mid-dose groups, mild, sporadic irritation was seen after 3 to 8 weeks of treatment. Signs included mild erythema with occasional desquamation. Hematuria (red urinary staining) was noted in one each mid- and high-dose female from week 7 through 13. No effects of treatment on estrous cycling or reproductive performance were evident.                           | 54 FR 32117; 8/4/89, Fiche# OTS0521735     |
| Diisodecyl phenyl phosphite           | 25550-98-5 | HENEUR Subchronic delayed neurotoxicity study                    | 40 CFR 798.6560 (modified) | White leghorn hens (mature) | oral (gavage), 5 d/wk; 4 wks                        | 0, 100, 1000, 4000 mg/kg/d  | 10            | Slight body weight loss was noted in the high dose group, and possible treatment-related mortality was noted at mid and high doses. No neurotoxic effects were apparent from antemortem evaluations, but microscopic examination showed distal, peripheral neuropathy in 2/10 high-dose hens.   | 55 FR 22947; 6/05/90, Fiche# OTS0532324    |
| Diisodecyl phenyl phosphite           | 25550-98-5 | HENEUR Neurotoxic esterase assay                                 | 40 CFR 798.6450 (modified) | White leghorn hens (mature) | oral (gavage), 1 d, or 5 d/wk for 1, 2, 3, or 4 wks | 0, 100, 1000, 4000 mg/kg/d  | 20            | No altered neurotoxic esterase values were evident at any dose level.   | 55 FR 22947; 6/05/90, Fiche# OTS0532324    |

## Results of Testing

| Chemical Name      | CAS No.  | Study Code/Type  | Protocol/Guideline   | Species  | Exposure   | Dose/Concentration                 | No. per Group                  | Results  | Reference                                      |
|--------------------|----------|--|--|--|--|------------------------------------|--------------------------------|--|--|
| Anthraquinone      | 84-65-1  | EEATOX<br>Fish acute toxicity  | 40 CFR 797.1400<br>(modified)                                | Rainbow trout                                    | 96 hr, flow-through  | 10, 18, 23, 35, 55 µg/L            | Not specified                  | Following 96 hours of exposure, no significant toxicant-related mortalities or adverse effects were observed among the test animals at any treatment level.  | 53 FR 45385;<br>11/11/88, Fiche#<br>OTS0521423 |
| Anthraquinone      | 84-65-1  | EEATOX<br>Fish acute toxicity  | 40 CFR 797.1400<br>(modified)                                | Coho salmon                                      | 96 hr, flow-through  | 12, 18, 24, 30, 45 µg/L            | Not specified                  | No significant toxicant-related mortalities or adverse effects were observed among the test animals at any of the concentration levels tested.   | 53 FR 45385;<br>11/11/88, Fiche#<br>OTS0521423 |
| Anthraquinone      | 84-65-1  | EEATOX<br>Fish acute toxicity  | 40 CFR 797.1400<br>(modified)                                | Bluegill sunfish                                 | 14 d, flow-through   | 12, 16, 23, 34, 48 µg/L            | Not specified                  | Following 14 days of exposure, there were no significant mortalities or adverse effects among the test animals.  | 54 FR 1989; 1/18/89,<br>Fiche# OTS0521424      |
| Anthraquinone      | 84-65-1  | EEATOX<br>Acute invertebrate toxicity                                  | 40 CFR 797.1300<br>(modified)                                | <i>Daphnia magna</i>                             | 48 hr, flow-through  | 6.9, 10, 18, 27, 48 µg/L           | Not specified                  | Following the 48 hours of exposure, there were no immobilization or adverse effects observed.  | 54 FR 1989; 1/18/89,<br>Fiche# OTS0521424      |
| Anthraquinone      | 84-65-1  | EEATOX<br>Acute invertebrate toxicity                                  | 40 CFR 797.1800<br>(modified)                                | Eastern oysters                                  | 96 hr, flow-through  | 6.0, 11, 17 µg/L                   | Not specified                  | Comparisons of biological response data did not establish a concentration-effect relationship at any of the concentrations tested. Shell deposition reduction among the test animals exposed to the highest concentration (17 µg/L) was 15% of control. Comparison of the response data did not establish a concentration-effect relationship within the range tested. | 54 FR 1989; 1/18/89,<br>Fiche# OTS0521424      |
| Anthraquinone      | 84-65-1  | EEATOX<br>Chironomid acute toxicity                                    | 40 CFR 795.4050<br>(modified)                                | <i>Chironomus tentans</i> (midge)                | 14 days, sediment  | 200 mg/kg of sediment<br>(nominal) | Not specified                  | A concentration-related adverse effect was not clearly shown; a no-effect level of 0.16 mg/L (interstitial water concentration) was identified. BCF factors ranged from 106x to 433x in high and low organic sediments, respectively.  | 54 FR 38436; 9/18/89,<br>Fiche# OTS0521426     |
| Anthraquinone      | 84-65-1  | EEBIOC<br>Mollusk bioconcentration                                     | 40 CFR 797.1830<br>(modified)                                | <i>Crassostrea virginica</i><br>(Eastern oyster) | 17 days; 14-day<br>depuration period,<br>flow-through seawater   | 0.75 and 10 µg/L<br>(nominal)      | Not specified                  | Steady state was reached within 24 hours. The mean steady-state BCFs were 110x and 140x for 0.75 and 10 µg/L concentrations, respectively  | 54 FR 14861;<br>4/13/89, Fiche#<br>OTS0521425  |
| Anthraquinone      | 84-65-1  | EFPCHEWSOL<br>Water solubility   | 40 CFR 796.1840B<br>(modified)                               | Not applicable                                   | Generator column,<br>well water, 12 and 22<br>°C. pH 5, 7 and 9. | 20, 50, 100, 150, 200<br>µg/L      | Not applicable                 | Water solubilities for pH 5.1 at 12 °C and at 22 °C were 54.3 µg/L and 119 µg/L, respectively. The water solubilities for pH 7.0 at 12 °C and pH 7.2 at 22 °C were 76.1 µg/L and 125 µg/L, respectively. The values for pH 9.0 at 12 °C and 22 °C were 93.7 µg/L and 151 µg/L, respectively.   | 53 FR 45385;<br>11/09/88, Fiche#<br>OTS0521423 |
| Diethylenetriamine | 111-40-0 | EFOTHR<br>Nitrosamine formation  | Non-TSCA Protocol/<br>Guideline (see docket<br>OPTS #42012D) | Not applicable                                   | sewage and soils   | Not specified                      | Not applicable                 | There were no N-nitrosamine at the detection limit (500 µg/L) from sewage and lake waters. The formation of N-nitrosamines from the test substance in soil could not be determined with confidence using the available analytical techniques due to the high background and variability.   | 56 FR 16333; 4/22/91<br>Fiche# OTS0531302      |
| Diethylenetriamine | 111-40-0 | HEGTOXCHRM<br>Mammalian bone<br>marrow chromosomal<br>aberration assay | Non-TSCA Protocol/<br>Guideline (see docket<br>OPTS #42012D) | mouse  | oral (gavage), single-<br>dose                                   | 0, 85, 283, 850 mg/kg<br>bw        | 5/sex/group/<br>sacrifice time | Groups of animals were sacrificed at 24, 48, and 72 hours after treatment. The high-dose level was approximately 60% of the oral LD50 value in mice. The treatment did not increase the frequency of micronucleated polychromatic erythrocytes, indicating that the test compound was not clastogenic in mice.   | 53 FR 19334; 5/27/88<br>Fiche# OTS0522092      |



## Results of Testing

| Chemical Name                          | CAS No.  | Study Code/Type   | Protocol/Guideline   | Species                                 | Exposure   | Dose/Concentration  | No. per Group         | Results   | Reference  |
|--|----------|---|--|---|--|---|-----------------------|---|--|
| Diethylenetriamine                     | 111-40-0 | HEGTOXCHRM<br>Mammalian<br>cytogenetics                           | Non-TSCA Protocol/<br>Guideline (see docket<br>OPTS #42012D) | Chinese<br>hamster, ovary<br>(CHO)      | <i>in vitro</i>  | 250, 833, 2500 µg/mL  | Not applicable        | There were no increases in the frequency of chromosomal<br>aberrations either in the absence or presence of metabolic<br>activation.  | 52 FR 37006;<br>10/02/87<br>Fiche# OTS0522081    |
| Diethylenetriamine                     | 111-40-0 | HEGTOXMUTA<br>Sex linked recessive<br>lethal assay                | Non-TSCA Protocol/<br>Guideline (see docket<br>OPTS #42012D) | <i>Drosophila</i>                       | oral   | 0 or 60 nM  | 25/group              | The treatment did not cause a statistically significant increase<br>in the frequency of sex-linked recessive lethals relative to<br>the negative control, indicating that the test substance was<br>not mutagenic to male germ cells in <i>Drosophila</i> .   | 53 FR 19334; 5/27/88<br>Fiche# OTS0522092        |
| Diethylenetriamine                     | 111-40-0 | HESTOX<br>Probe feeding study                                     | Non-TSCA Protocol/<br>Guideline (see docket<br>OPTS #42012D) | albino rats                             | 14-day probe feeding<br>study  | 0, 5000, 10,000, 25,000,<br>50,000 ppm  | 10/sex/group          | Clinical observations revealed piloerection in high-dose<br>males and females. Significantly reduced food consumption<br>rates were observed in both sexes at the two high-dose<br>levels; and significantly reduced mean body weights were<br>observed in males at the two high-dose levels and in females<br>at the 3 high-dose levels. Significantly reduced mean and<br>relative spleen weights were observed in both sexes at the<br>two high-dose levels.   | 52 FR 2152; 1/20/87<br>Fiche# OTS0522079         |
| Diethylenetriamine                     | 111-40-0 | HESTOX<br>Subchronic toxicity                                     | 40 CFR 798.2650  | rats                                    | oral (dietary), 90 d   | 0, 70, 530,<br>1060 mg/kg/d (male)<br>0, 80, 620, 1210<br>mg/kg/d (female); 4 wk<br>recovery period | 30 male;<br>30 female | Decreased food consumption was observed throughout the<br>dosing period for test animals in the 530-620 dose range<br>(males and females). Dose-related decreases in body weight<br>gain was observed in both sexes in the mid-and high-dose<br>groups. Clinical observations for males in the mid-to high-<br>dose level were increased MCV (mean corpuscular volume)<br>and MCH (mean corpuscular hemoglobin) levels.<br>Observations for females in the mid-to high-dose levels<br>included; decreased glucose and albumin levels, increased<br>MCV and MCH, increased urine pH, and increased kidney<br>weight. | 53 FR 25008; 7/1/88<br>Fiche# OTS0522093         |
| Mesityl Oxide                          | 141-79-7 | HEGTOXCHRM<br>Mammalian bone<br>marrow micronucleus<br>assay      | 40 CFR 798.5395  | mice                                    | parenteral   | 170, 340, 680 mg/kg   | 5/sex                 | Bone marrow depression was observed at 72 hours in high<br>dose males; Bone marrow depression was negative for<br>females.  | 57 FR 29319; 7/01/92;<br>Docket# OPPTS-<br>44588 |
| Mesityl Oxide                          | 141-79-7 | HEGTOXMUTA<br>Reverse mutation<br>assay                           | 40 CFR 798.5265  | <i>Salmonella</i><br><i>typhimurium</i> | <i>in-vitro</i>  | 100-5000 µg/plate   | Not applicable        | The test material is negative for mutagenic activity under the<br>conditions of this study.   | 57 FR 29319; 7/01/92;<br>Docket# OPPTS-<br>44588 |
| Mesityl Oxide                          | 141-79-7 | HERTOXTERA<br>Combined<br>developmental/<br>reproduction toxicity | Non-TSCA Protocol/<br>Guideline (see docket<br>#44592)       | rats                                    | inhalation; 6 hr/d, 7<br>d/wk for 36 to 49<br>exposures (females)<br>and 49 exposures<br>(males) | 31, 103, 302 ppm  | 12/sex                | No mortality was observed throughout the study. Reduction<br>in food consumption, body weight and body weight gain, and<br>nasal discharge were observed at all dose levels. Reduced<br>activity, sialorrhea, focal chronic inflammation, and a<br>reduced number of dams that delivered a litter were observed<br>at 302 ppm. The LOAEC for maternal toxicity was 31 ppm.<br>The NOEC for reproductive toxicity was 103 ppm.   | 57 FR 53898;<br>11/13/92; Docket#<br>OPPTS-44592 |
| Triethylene glycol<br>monomethyl ether | 112-35-6 | HEGTOXCHRM<br>Mammalian bone<br>marrow micronucleus<br>assay      | 40 CFR 798.5385  | mice                                    | oral (gavage), single<br>dose  | 0, 500, 1667, 5000<br>mg/kg/d   | 5/sex                 | No evidence of clastogenicity was seen.   | 55 FR 13956; 5/13/90,<br>Fiche# OTS052647        |

## Results of Testing

| Chemical Name                       | CAS No.  | Study Code/Type                              | Protocol/Guideline        | Species                       | Exposure   | Dose/Concentration  | No. per Group  | Results  | Reference                               |
|-------------------------------------|----------|--|---------------------------|-------------------------------|--|---|----------------|--|---|
| Triethylene glycol monomethyl ether | 112-35-6 | HEGTOXMUTA<br>Reverse mutation assay         | 40 CFR 798.5265           | <i>Salmonella typhimurium</i> | <i>in vitro</i>                                      | ranged from 50 to 5000 µg/plate                                     | Not applicable | Tests in strains TA98, TA100, TA1535, and TA1537 did not increase mutation frequencies in any assay up to the limit of cytotoxicity, with or without activation.   | 55 FR 13956; 5/13/90, Fiche# OTS0526547 |
| Triethylene glycol monomethyl ether | 112-35-6 | HEGTOXMUTA<br>Mutagenicity study             | 40 CFR 798.5300           | chinese hamsters, ovary (CHO) | <i>in vitro</i>                                      | ranged from 2000 to 5000 µg/L                                       | Not applicable | Treatment did not increase mutation frequencies in any assay, with or without activation.  | 55 FR 13956; 5/13/90, Fiche# OTS0526547 |
| Triethylene glycol monomethyl ether | 112-35-6 | HENEUR<br>Developmental neurotoxicity screen | 40 CFR 795.250 (modified) | rats                          | oral (gavage), gestational day 6 to postnatal day 21 | 0, 300, 1650, 3000 mg/kg/d  | 16/group       | Under the conditions of this study, the test substance was not associated with any treatment-related histopathologic lesions. The results of this study clearly demonstrate the ability of the motor activity, auditory startle, and active avoidance systems in use.  | 57 FR 11614; 4/06/92, OTS0000842        |
| Triethylene glycol monomethyl ether | 112-35-6 | HENEUR<br>Neuropathology                     | 40 CFR 798.6400           | rats                          | oral (drinking water), 90 days                       | 0, 0.4, 1.2, 4.0 g/kg/d   | 15/sex/group   | Treatment with the test substance did not result in clinical signs of toxicity, alterations in the functional observational battery, or gross or microscopic lesions in the nervous system. Decreased food consumption, body weight and body weight gain was seen at the two highest doses. Minor decreases in motor activity was observed in the high-dose group at day 60 (males) and day 90 (both sexes). Treatment produced moderate toxicity at 4.0 g/kg/day and mild toxicity at 1.2 g/kg/day. The test substance was determined not to produce neurotoxicity at doses as high as 4.0 g/kg/day. The no-observable-effect-level for neurotoxicity is at least 4.0 g/kg/day. | 55 FR 50055; 12/4/90, Fiche# OTS0530838 |
| Triethylene glycol monomethyl ether | 112-35-6 | HENEUR<br>Functional observational battery   | 40 CFR 798.6200           | rats                          | oral (drinking water), 14 day                        | 0, 0.75, 1.6, 3.9, 8.0 g/kg/d (actual doses, time weighted average) | 10 males       | Decreased mean hind limb grip strength and mean rearing events were noted in high-dose rats.   | 55 FR 50055; 12/04/90,                  |
| Triethylene glycol monomethyl ether | 112-35-6 | HENEUR<br>Motor activity                     | 40 CFR 798.6200           | rats                          | oral (drinking water), 90 d                          | 0, 0.4, 1.2, 4.0 g/kg/d   | 15/sex/group   | Treatment with the test substance did not result in clinical signs of toxicity, alterations in the functional observational battery, or gross or microscopic lesions in the nervous system. Decreased food consumption, body weight and body weight gain was seen at the two highest doses. Minor decreases in motor activity was observed in the high-dose group at day 60 (males) and day 90 (both sexes). Treatment produced moderate toxicity at 4.0 g/kg/day and mild toxicity at 1.2 g/kg/day. The test substance was determined not to produce neurotoxicity at doses as high as 4.0 g/kg/day. The no-observable-effect-level for neurotoxicity is at least 4.0 g/kg/day. | 55 FR 50055; 12/4/90, Fiche# OTS0530838 |
| Triethylene glycol monomethyl ether | 112-35-6 | HERTOXTERA<br>Developmental toxicity         | 40 CFR 798.4900           | rabbits                       | oral (gavage), gestation day 6-18                    | 0, 250, 500, 1000, 1500 mg/kg/d                                     | 20 females     | Maternal toxicity occurred at 1000 mg/kg/day (death of one doe). High-dose dams had clinical signs, decreased body weight, and food consumption. High-dose fetuses had increased incidences of delayed skeletal ossification of the xiphoid. The NOEL for both maternal and developmental toxicity was 500 mg/kg/day.  | 55 FR 17670; 5/26/90, Fiche# OTS0526548 |

## Results of Testing

| Chemical Name                       | CAS No.  | Study Code/Type                           | Protocol/Guideline | Species                                     | Exposure                             | Dose/Concentration  | No. per Group  | Results  | Reference                                      |
|-------------------------------------|----------|---|--------------------|---|--------------------------------------|---|----------------|--|--|
| Triethylene glycol monomethyl ether | 112-35-6 | HERTOXTERA<br>Developmental toxicity      | 40 CFR 798.4900    | rats  | oral (gavage),<br>gestation day 6-15 | 0, 625, 1250, 2500,<br>5000 mg/kg/d                                       | 25 females     | Maternal toxicity (decreased food consumption) was seen in the 2500 and 5000 mg/kg/day group; one high-dose dam died, and others showed clinical signs, and decreased body weight gain and gravid uterine weights. Decreased fetal weight was seen at 2500 mg/kg/day and higher. The NOEL for maternal and developmental toxicity was 625 mg/kg/day.   | 55 FR 17670; 5/26/90,<br>Fiche# OTS0526548     |
| Triethylene glycol monomethyl ether | 112-35-6 | HESTOX<br>Subchronic dermal toxicity      | 40 CFR 798.2250    | rats  | dermal, 13 wks                       | 0, 400, 1200, 4000<br>mg/kg/d   | 10/sex/group   | The only treatment-related effects noted in this study consisted of focal areas of dermal irritation in all animals treated. The no-observed-effect-level (NOEL) for systemic toxicity was 4000 mg/kg bw/day.  | 55 FR 50055;<br>12/04/90, Fiche#<br>OTS0530838 |
| Triethylene glycol monomethyl ether | 112-35-6 | HESTOX<br>Subchronic toxicity             | 40 CFR 798.2650    | rats  | oral (drinking water),<br>14 days    | 0, 0.75, 1.6, 3.9, 8.0<br>g/kg/d (actual doses,<br>time weighted average) | 10 males       | No mortalities occurred. Dose-related decreased mean food consumption and body weight gain were noted at 3.9 g/kg/day and higher. High-dose animals also showed clinical signs indicative of general debilitation and malaise (including functional observational battery signs, general cachexia, gait alterations, and piloerection); necropsy revealed lung discoloration. The NOEL was 1.6 g/kg/day.   | 55 FR 50055;<br>12/04/90,<br>Fiche# OTS0526547 |
| 1,2-Dichloro-propane                | 78-87-5  | EEATOX<br>Algae acute toxicity            | 40 CFR 797.1050    | <i>Skeletonema costatum</i><br>(algae)      | 5 days                               | 10, 18, 32, 56, 100 mg/L<br>(nominal)                                     | Not applicable | Although a general trend of decreasing algal population growth with increasing nominal concentrations of the test substance was observed, the measured concentrations for each nominal value display sufficient variability that it is not appropriate to determine EC values. There were no significant differences between the mean cell counts in the 10 and 18 mg/L concentrations and the control on any of the exposure days. Thus, the no-observed-effect-concentration (NOEC) across all exposure days is 18 mg/L. It was not possible to distinguish algistatic from algicidal effects.   | 53 FR 49227; 12/6/88<br>Fiche# OTS0527733      |
| 1,2-Dichloro-propane                | 78-87-5  | EEATOX<br>Algae acute toxicity            | 40 CFR 797.1050    | <i>Selenastrum capricornutum</i><br>(algae) | 5 days                               | 100, 180, 320, 560,<br>1000 mg/L (nominal)                                | Not applicable | Although a weak trend of decreasing algal population growth with increasing concentrations of the test substance was observed for some sampling days, the measured concentrations for each value display sufficient variability that it is not appropriate to determine EC values. There were no significant differences between the mean cell counts in any of the test concentrations and the control on exposure days 2, 4, and 5. Thus, the no-observed-effect-concentration (NOEC) for these exposure days is 1000 mg/L. The mean cell counts in the 180, 560, and 1000 mg/L test concentrations on day 3 were significantly different from that in the control, although the mean cell count in the 320 mg/L was not. The test material did not exhibit any algistatic or algicidal effects. | 53 FR 49227; 12/6/88<br>Fiche# OTS0527733      |
| 1,2-Dichloro-propane                | 78-87-5  | EEATOXCRST<br>Mysid shrimp acute toxicity | 40 CFR 797.1930    | mysid shrimp                                | flow-through, 96-hr                  | 0, 6.5, 10.8, 18, 30, 50<br>mg/L (nominal)                                | Not applicable | Results indicate that the 24-hour old mysids have a 96-hour LC <sub>50</sub> value of 24.79 mg/L and the NOEL is 4.92 mg/L with no sublethal effects observed during the test. The 3-4 day old mysids have a 96-hour LC <sub>50</sub> value greater than 26.65 mg/L and the NOEL is 4.92 mg/L.   | 53 FR 49227; 12/6/88<br>Fiche# OTS0527733      |

## Results of Testing

| Chemical Name        | CAS No. | Study Code/Type                            | Protocol/Guideline                | Species                                | Exposure                   | Dose/Concentration   | No. per Group          | Results   | Reference  |
|----------------------|---------|--|-----------------------------------|--|----------------------------|--|------------------------|---|--|
| 1,2-Dichloro-propane | 78-87-5 | EECTOX<br>Chronic toxicity in daphnids     | 40 CFR 797.1330                   | <i>Daphnia magna</i>                   | flow-through, 21 days      | 0, 7.5, 12, 21, 36, 60 mg/L (nominal)  | Not applicable         | Exposure to the test substance resulted in a 21-day no observed effect level (NOEL) is 8.3 mg/L. The lowest observed effect level (LOEL) is 15.8 mg/L. The maximum acceptable toxicant concentration (MATC) is 11.4 mg/L.   | 53 FR 49227; 12/6/88<br>Fiche# OTS0527733                    |
| 1,2-Dichloro-propane | 78-87-5 | EECTOXRST<br>Mysid shrimp chronic toxicity | 40 CFR 797.1390                   | <i>Mysidopsis bahia</i> (mysid shrimp) | flow-through, 28 days      | 0.41, 0.97, 1.35, 2.48, and 4.09 mg/L  | Not specified          | A LOEC was not established due to lack of any significant effects on G <sub>1</sub> mysid survival, growth, or reproduction. The NOEC was 4.09 mg/L. Therefore, the MATC was > 4.09 mg/L, the highest concentration tested.   | 54 FR 11273; 3/17/89,<br>OPTS0527735,<br>Docket# OPPTS-44527 |
| 1,2-Dichloro-propane | 78-87-5 | HEADME<br>Pharmacokinetics studies         | 40 CFR 795.230 (modified)         | rat                                    | oral (gavage), single-dose | 1 or 100 mg/kg/day   | 4/sex/group            | Following administration of the test substance, between 91 and 107% of the administered radioactivity was recovered. The main routes of elimination were the urine (50%), expired air (30%), feces (6%), and cage washes (3%). The test substance was widely distributed among organs and tissues, with the liver containing the most radioactivity. The majority of the urinary, pulmonary, and fecal elimination of radioactivity occurred in the first 24-hours after dosing. Labeled DCP comprised 82% of the <sup>14</sup> C exhaled at the 100 mg/kg dose. Three of 4 metabolites detected in urine were mercapturic acid metabolites.  | 54 FR 21282; 5/17/89<br>OTS527713                            |
| 1,2-Dichloro-propane | 78-87-5 | HEADME<br>Pharmacokinetics studies         | 40 CFR 795.230 (modified)         | rat                                    | oral, gavage, 1/d, 8 days  | 1 mg/kg/day (non-labeled) for 7-days; on the 8th day rats received 1 mg/kg/day (labeled) | 4/sex/group            | Following administration of the test substance, 96% of the administered radioactivity was recovered. The main routes of elimination were the urine (44%), expired air (55%), feces (6%), and cage washes (3%). The test substance was widely distributed among organs and tissues, with the liver containing the most radioactivity. The majority of the urinary, pulmonary, and fecal elimination of radioactivity occurred in the first 24-hours after dosing. Three of the four metabolites detected in urine were mercapturic acid metabolites.   | 54 FR 21282; 5/17/89<br>OTS527713                            |
| 1,2-Dichloro-propane | 78-87-5 | HEADME<br>Pharmacokinetics studies         | 40 CFR 795.230 (modified)         | rat                                    | inhalation, 6 hrs          | 0, 5, 50, 100 ppm  | 4/sex/group            | The main routes of elimination were the urine (60%) and expired air (20%). As the exposure concentration increased, the amount of exhaled volatile organics increased. The liver and kidneys had a greater amount of radioactivity among the tissues analyzed. The feces represented a minor excretory pathway (8%). The majority of the urinary, pulmonary, and fecal elimination of radioactivity occurred in the first 24-hours after dosing. Half-life elimination from blood was 30 and 24 minutes for males and females, respectively. Dose-related peak plasma concentrations were observed 4 hours after exposure. Analysis of urine revealed 5 metabolites, no parent compound was identified. Three of the metabolites detected in urine were mercapturic acid metabolites. | 54 FR 21282; 5/17/89<br>OTS527713                            |
| 1,2-Dichloro-propane | 78-87-5 | HECTOXCARC<br>Carcinogenicity Study        | National Toxicology Program (NTP) | F344/N rats                            | gavage, 5/wk, 103 weeks    | 0, 62, 125 mg/kg (males); 0, 125, 250 mg/kg (females)                                    | 50 males<br>50 females | No evidence of carcinogenicity for male rats at all dose levels. There was equivocal evidence of carcinogenicity in female rats at the 250 mg/kg level based on a marginally increased incidence of adenocarcinomas in the mammary gland which occurred concurrent with decreased survival and reduced body weight.   | NTP TR-263, April 1986; NTIS PB 871114443/AS                 |

## Results of Testing

| Chemical Name        | CAS No. | Study Code/Type                            | Protocol/Guideline | Species                 | Exposure                              | Dose/Concentration                          | No. per Group          | Results  | Reference                                    |
|----------------------|---------|--|--------------------|-------------------------|---------------------------------------|---|------------------------|--|--|
| 1,2-Dichloro-propane | 78-87-5 | HECTOXCARC<br>Carcinogenicity Study        | NTP                | B6C3F <sub>1</sub> mice | gavage, 5/wk, 103 weeks               | 125, 250 mg/kg                              | 50 males<br>50 females | There was some evidence of carcinogenicity for male and female mice as indicated by increased incidences of hepatocellular neoplasms, primarily adenomas.  | NTP TR-263, April 1986; NTIS PB 871114443/AS |
| 1,2-Dichloro-propane | 78-87-5 | HEGTOXCHRM<br>Rodent dominant lethal assay | 40 CFR 798.5450    | rats                    | oral (diet), 14 wks                   | 0, 0.024, 0.10, 0.24%                       | 30/males/group         | Treated male rats were mated to pairs of untreated adult females each week for 2-weeks. Female rats were killed 14-days after the middle of the breeding period for evaluation of dominant lethal effects by measurement of the resorption rate. High-dose males had decreased water consumption and mid- and high-dose males had decreased body weight. The treatment had no adverse effects on male fertility as determined by mating performance and resorption rate. The treatment did not induce a dominant lethal effect, indicating that the test substance was not mutagenic to male germ cells. | 54 FR 25167; 6/13/89<br>OTS527736            |
| 1,2-Dichloro-propane | 78-87-5 | HENEUR<br>Functional observational battery | 40 CFR 798.6050    | rats                    | oral (gavage), 5 d/wk for 13 wks      | 0, 20, 65, 200 mg/kg/day                    | 15/sex/group           | Clinical signs of high-dose males included depressed weight gain and was also noted in mid-dose males and high-dose females. No effects were noted upon the functional observation battery, hind limb grip strength, or motor activity at any of the monthly intervals throughout the study. No gross or histopathologic effects on the nervous system, either central or peripheral, were demonstrated.   | 53 FR 49227; 12/06/88<br>Fiche# OTS0527733   |
| 1,2-Dichloro-propane | 78-87-5 | HENEUR<br>Motor activity                   | 40 CFR 798.6200    | rats                    | oral (gavage), 2 wks                  | 0, 300, 500 mg/kg/d                         | 10 male;<br>10 female  | Observations included tearing, blinking, and lethargy (300 and 500 mg/kg). There were no statistically significant differences in motor activity between treated and control animals.  | 53 FR 49227; 12/6/88<br>Fiche# OTS0517725    |
| 1,2-Dichloro-propane | 78-87-5 | HENEUR<br>Neuropathology                   | 40 CFR 798.6400    | rats                    | oral (gavage), 2 wks                  | 0, 300, 500 mg/kg/d                         | 10 male;<br>10 female  | Decreased respiration was noted in 4 females in each treatment group. There were no effects on hematologic values. Liver and kidney weights were increased in treated test animals.  | 53 FR 49227; 12/6/88<br>Fiche# OTS0517725    |
| 1,2-Dichloro-propane | 78-87-5 | HERTOXTERA<br>Developmental toxicity       | 40 CFR 798.4900    | rabbits                 | oral (gavage), days 7-19 of gestation | 0, 25, 100, 250 mg/kg                       | 7 pregnant females     | Mortality increased in the 250 mg/kg/day dose group. Treatment-related anemia was observed in both the 100 and 250 mg/kg/day dose groups. This was evident by decreased hematocrit, hemoglobin concentration, and red blood cell count. There was an increase in the reabsorption rate at the 250 mg/kg/day dose level.  | 54 FR 21282; 5/17/89<br>Fiche# OTS0516583    |
| 1,2-Dichloro-propane | 78-87-5 | HERTOXTERA<br>Developmental toxicity       | 40 CFR 798.4900    | rats                    | oral (gavage), days 6-15 of gestation | 0, 50, 125, 250, 500 mg/kg/d                | 10 pregnant females    | Treatment with test material produced statistically significant lower body weights at 125 and 500 mg/kg/day. Sight decreases in mean red blood cell number, hemoglobin concentration, and hematocrit were noted at 500 mg/kg/day. No signs of embryolethality or reproductive effects were noted.  | 54 FR 25167; 6/13/89<br>Fiche# OTS0516720    |
| 1,2-Dichloro-propane | 78-87-5 | HERTOXTERE<br>Reproductive/fertility study | 40 CFR 798.4700    | rats                    | oral (drinking water), 2 generations  | 0, 0.024, 0.10, 0.24% (limit of solubility) | 30/sex/<br>generation  | Concentration-related reduced water consumption and weight gain were noted. No gross pathological effects were seen at any level, but increased hepatocellular granularity was noted in both generations. High-exposure animals of both generations had litters with reduced neonatal body weights and survival rates.   | 55 FR 27303; 7/02/90<br>Fiche# OTS0527738    |

## Results of Testing

| Chemical Name     | CAS No.  | Study Code/Type  | Protocol/Guideline   | Species                                 | Exposure                                | Dose/Concentration  | No. per Group         | Results   | Reference                                 |
|-------------------|----------|--|--|---|---|---|-----------------------|---|---|
| Tetrafluoroethene | 116-14-3 | HECTOXCARC<br>Carcinogenesis study                           | National Toxicology<br>Program (NTP)                         | F344 rats                               | inhalation, 6 hr/day, 5<br>d/wk, 103 wk | 156, 312, 625 ppm<br>(male); 312, 625, 1250<br>ppm (female)                     | 60 male and<br>female | Clear evidence of carcinogenic activity of TFE in male rats based on increased incidence of renal tube neoplasms (mainly adenomas) and hepatocellular neoplasms. Clear evidence of carcinogenic activity of TFE in female rats based on increased incidence of renal tube neoplasms, liver hemangiosarcomas, hepatocellular neoplasms, and mononuclear cell leukemia. Increased incidences of renal tubule degeneration and hyperplasia in males and females, increased severity of kidney nephropathy in males, and liver angiectasis and cataracts in females were also noted. There were also slight increased in the incidence of mononuclear cell leukemia and testicular interstitial cell adenomas in males. | NTP TR-450 (Draft),<br>December, 1995     |
| Tetrafluoroethene | 116-14-3 | HECTOXCARC<br>Carcinogenesis study                           | NTP  | B6C3F <sub>1</sub> mice                 | inhalation, 6 hr/day, 5<br>d/wk, 95 wk  | 0, 312, 625, 1250 ppm   | 58 male and<br>female | Clear evidence of carcinogenic activity of TFE in male and female mice based on increased incidences of liver hemangiomas and hemangiosarcomas, hepatocellular neoplasms, and histiocytic sarcomas. There was also an increased incidence of renal tubule karyomegaly in males and females, renal tubule dilatation in males, liver angiectasis in males and females, hematopoietic cell proliferation of the liver in females and splenic hematopoietic cell proliferation in males and females.   | NTP TR-450 (Draft),<br>December, 1995     |
| Tetrafluoroethene | 116-14-3 | HEGTOXCHRM<br>Mammalian bone<br>marrow micronucleus<br>assay | 40 CFR 798.5460<br>(modified)                                | mice                                    | inhalation, whole<br>body, 6 hr         | 0, 5000, 12000, 19000<br>ppm (males); 0, 7000,<br>17000, 28000 ppm<br>(females) | 5/sex                 | Treatment did not increase the frequency of micronuclei in females. In males, the frequency was slightly increased at low and mid-treatment levels at the 72-hour sampling time, only.  | 53 FR 20685; 6/6/88<br>Fiche# OTS05228091 |
| Tetrafluoroethene | 116-14-3 | HEGTOXMUTA<br>Mutagenicity study                             | 40 CFR 798.5300<br>(modified)                                | Chinese<br>hamster ovary<br>cells (CHO) | <i>in vitro</i>                         | 0, 20, 40, 60, 80, 100%<br>(atmospheric<br>concentrations)                      | Not applicable        | Treatment at up to cytotoxic levels did not increase the frequency of mutations at the HPRT locus in the presence or absence of Aroclor-induced rat liver homogenate.   | 53 FR 19334; 5/27/88<br>Fiche# OTS0522807 |
| Hexafluoropropene | 116-15-4 | HEGTOXCHRM<br>Rodent dominant<br>lethal assay                | 40 CFR 798.5450<br>(modified)                                | rat                                     | inhalation, 6 hr/d, 5 d                 | 0, 25, 100, 400 ppm   | Not specified         | Treatment at up to toxic levels did not increase the frequency of dominant lethal mutations.  | 53 FR 45385; 11/9/88<br>Fiche# OTS0522791 |
| Hexafluoropropene | 116-15-4 | HEGTOXMUTA<br>Mutagenicity study                             | 40 CFR 798.5300<br>(modified)                                | Chinese<br>hamster ovary<br>cells (CHO) | <i>in vitro</i>                         | 0, 0.1, 0.25, 0.50, 1.00,<br>1.50% (atmospheric<br>concentrations)              | Not applicable        | Treatment at up to cytotoxic levels did not increase the frequency of mutations at the HPRT locus in the presence or absence of Aroclor-induced rat liver homogenate.   | 53 FR 37643; 9/27/88<br>Fiche# OTS0522811 |
| Hexafluoropropene | 116-15-4 | HEGTOXMUTA<br>Mutagenicity study                             | 40 CFR 798.5300<br>(modified)                                | Chinese<br>hamster ovary<br>cells (CHO) | <i>in vitro</i>                         | 0, 0.05, 0.15, 0.20, 0.30,<br>0.35% (atmospheric<br>concentrations)             | Not applicable        | Treatment at up to cytotoxic levels did not increase the frequency of mutations at the HPRT locus in the presence or absence of Aroclor-induced rat liver homogenate.   | 53 FR 19334; 5/27/88<br>Fiche# OTS0522806 |
| Hexafluoropropene | 116-15-4 | HEGTOXMUTA<br>Mutagenicity study<br>(voluntary test)         | Non-TSCA Protocol/<br>Guideline (see docket<br>#OPTS-42002E) | Chinese<br>hamster ovaries<br>(CHO)     | <i>in vitro</i>                         | 0, 0.03, 0.08, 0.41, 0.74,<br>1.13, 2.5% (v/v)                                  | Not applicable        | There were no increases in mutagenic activity induced by exposure to the test material either in the presence or absence of metabolic activation.   | 51 FR 16203; 5/1/86<br>Fiche# OTS0512564  |
| Hexafluoropropene | 116-15-4 | HESTOX<br>Subchronic inhalation<br>toxicity                  | 40 CFR 798.2450<br>(modified)                                | mice                                    | whole body, 6 hr/d,<br>5 d/wk, 13 wks   | 0, 10, 50, 150 ppm<br>(target)  | 25/sex                | Kidney lesions were seen at 50 and 150 ppm in both sexes, and these could still be seen throughout the 28 day observation period. No other effects were reported.   | 54 FR 8816; 3/2/89<br>Fiche# OTS0522814   |

## Results of Testing

| Chemical Name     | CAS No.  | Study Code/Type  | Protocol/Guideline         | Species                        | Exposure  | Dose/Concentration          | No. per Group | Results  | Reference                                    |
|-------------------|----------|--|----------------------------|--------------------------------|---|-----------------------------|---------------|--|--|
| Hexafluoropropene | 116-15-4 | HESTOX<br>Subchronic inhalation toxicity                     | 40 CFR 798.2450 (modified) | rat                            | whole body, 6 hr/d, 5 d/wk, 13 wks                                  | 0, 10, 50, 150 ppm (target) | 20/sex        | High-dose males showed increased water consumption and decreased lymphocyte count. Urinalysis showed increased fluoride ions in both sexes at 50 ppm and above. These rats also had polyuria and low urine osmolality.   | 54 FR 8816; 3/2/89<br>Fiche# OTS0522814      |
| Vinyl fluoride    | 75-02-5  | HECTOXCARC<br>Oncogenicity study                             | 40 CFR 798.3300 (modified) | mice                           | inhalation, 6 hr/d, 5 d/wk, 18-months                               | 0, 25, 250, 2500 ppm        | 95/sex        | Survival was decreased in male mice of the 250 and 2500 ppm groups and female mice of all groups. At necropsy, the following observations were made: nodules, masses and discoloration of the lung, and fluid in the plural cavity; masses of the peritoneal cavity and hemorrhage, cysts, masses, discoloration and nodules of the liver; and mammary gland masses. Microscopically, these lesions were correlated with bronchioloalveolar adenoma and hyperplasia; hepatic hemangiosarcoma and hepatocellular hyperplasia with angiectasis and peliosis; and mammary gland adenocarcinoma and hyperplasia. The incidence of these lesions were concentration-related in all exposed groups. The test substance was determined to be carcinogenic in both sexes at concentrations greater than 25 ppm.                | 57 FR 37541; 8/19/92,<br>Docket# OPPTS-44590 |
| Vinyl fluoride    | 75-02-5  | HECTOXCARC<br>Oncogenicity study                             | 40 CFR 798.3300 (modified) | rat                            | inhalation, 6 hr/d, 5 d/wk, 2 years                                 | 0, 25, 250, 2500 ppm        | 95/sex        | Survival was decreased in male rats of the 250 and 2500 ppm groups and female rats of all groups. At necropsy, the following observations were made: masses, nodules, discoloration and hemorrhage of the liver; mass/nodules and discoloration of the lungs, and fluid of the peritoneal cavity; and masses of the head, face and periaural area; and abscesses of the face. Microscopically, these lesions were correlated with hepatic hemangiosarcoma, hepatocellular adenoma and carcinoma, foci of clear cell and basophilic alteration, and sinusoidal dilation, metastatic lung tumors, and Zymbal's gland tumors. The incidence of these lesions were concentration-related in all exposure groups. The test substance was determined to be carcinogenic in both sexes at concentrations greater than 25 ppm. | 57 FR 37541; 8/19/92,<br>Docket# OPPTS-44590 |
| Vinyl fluoride    | 75-02-5  | HEGTOXCHRM<br>Rodent dominant lethal assay                   | 40 CFR 798.5450 (modified) | rat                            | inhalation, 6 hr/d, 5 d   | 0, 200, 2000, 20,000 ppm    | Not specified | Treatment did not increase the frequency of dominant lethal mutations, nor were there signs of toxicity.   | 53 FR 43267; 10/26/88<br>Fiche# OTS0522790   |
| Vinyl fluoride    | 75-02-5  | HEGTOXDNAF<br>DNA damage in mammalian cells (voluntary test) | 40 CFR 798.5510 (modified) | rat                            | <i>in vivo</i> inhalation, 6 hr/day, on 1, 2, or 5 consecutive days | 0, 20,000 ppm               | 4 males       | Examination of rat testicular DNA using the alkaline elution method of detection showed no increase in single strand breaks, nor increased DNA cross links following exposure.   | 56 FR 1633; 4/22/91<br>Fiche# OTS0532956     |
| Vinyl fluoride    | 75-02-5  | HEGTOXDNAF<br>Unscheduled DNA synthesis (voluntary test)     | 40 CFR 798.5550 (modified) | rat                            | <i>in vivo</i> inhalation, 6 hr/d for 1, 2, or 5 consecutive days   | 20,000 ppm                  | 15 males      | Vinyl fluoride did not induce unscheduled DNA synthesis in this assay.   | 56 FR 2178; 1/22/91<br>Fiche# OTS0532955     |
| Vinyl fluoride    | 75-02-5  | HEGTOXMUTA<br>Sex linked recessive lethal study              | 40 CFR 798.5275 (modified) | <i>Drosophila melanogaster</i> | inhalation, 24 hr   | 0, 47.6%                    | Not specified | Statistically increased (p<0.01) sex-lined recessive lethals were noted in the treatment group.  | 53 FR 33537; 8/31/88<br>Fiche# OTS0522809    |

## Results of Testing

| Chemical Name       | CAS No.  | Study Code/Type   | Protocol/Guideline  | Species                        | Exposure                                    | Dose/Concentration                 | No. per Group    | Results  | Reference   |
|---------------------|----------|---|---|--------------------------------|---|------------------------------------|------------------|--|---|
| Vinylidene fluoride | 75-38-7  | HECTOXCARC<br>Oncogenicity study                          | 40 CFR 798.3300<br>(modified)                             | mice                           | inhalation, 16 months                       | Not specified                      | Not specified    | Summary information indicates survival had decreased to about 80% among high-exposure males and to about 78% in mid-exposure females.  | Fiche# OTS0532940   |
| Vinylidene fluoride | 75-38-7  | HEGTOXCHRM<br>Mammalian bone marrow micronucleus assay    | 40 CFR 798.5395<br>(modified)                             | mice                           | inhalation, 6 hr                            | 0, 5198, 15620, 41550 ppm          | 5/sex            | Treatment did not increase the frequency of micronuclei, nor did it induce signs of toxicity.  | 53 FR 49227; 12/6/88<br>Fiche# OTS0522784                         |
| Vinylidene fluoride | 75-38-7  | HEGTOXMUTA<br>Sex linked recessive lethal study           | 40 CFR 798.5275<br>(modified)                             | <i>Drosophila melanogaster</i> | inhalation, 24 hr                           | 0, 5.1, 21.8, 42.8% in air         | Not specified    | Treatment did not affect the percentage of sex-linked recessive lethals.   | 53 FR 33537; 8/31/88<br>Fiche# OTS0522810                         |
| Vinylidene fluoride | 75-38-7  | HESTOX<br>Subchronic inhalation toxicity                  | 40 CFR 798.2450<br>(modified)                             | mice                           | 6 hr/day, 5 d/wk, 13 wks                    | 0, 1000, 7000, 40,000 ppm          | 10/sex           | Increased mean corpuscular hemoglobin concentration was noted in high-exposure males, rough coat and sensitivity to touch in high-level males and mid- and high-level females, and increased locomotor activity in both sexes of all groups.   | 54 FR 12953; 3/29/89<br>Fiche# OTS0522815                         |
| Vinylidene fluoride | 75-38-7  | HESTOX<br>Subchronic inhalation toxicity (voluntary test) | Non-TSCA Protocol/<br>Guideline (see docket #OPTS-42002E) | rat                            | whole body, 6 hr/d, 5 d/wk, 13 wks          | 0, 1000, 7000, 40,000 ppm (target) | 30/sex           | Vacuolar degeneration of the vomeronasal gland was seen in all treatment groups. Decreased body weight gain, anemia, and decreased white blood cell count were seen at mid- and high-dose levels. Altered relative weights of spleen, testes, heart, and lung were noted in high-dose animals.   | 51 FR 27598; 8/1/86<br>Fiche# OTS0522774                          |
| 2-Ethylhexanol      | 104-76-7 | HECTOXCARC<br>Oncogenicity study                          | 40 CFR 798.3300<br>(modified)                             | mice                           | oral (gavage), 18 months                    | 0, 50, 200, 750 mg/kg/d            | 50/sex           | No substance related changes were seen at 50 or 200 mg/kg/day. At 750 mg/kg/day, reduced body weight gain related to decreased food consumption and increased mortality were noted; also a treatment-related hematological changes and slight, but not statistically significant, increase was noted in focal hyperplasia of the epithelium of the forestomach. No statistically-significant increases were noted in tumor incidence. 2-EH was not oncogenic in the mouse under the conditions of the assay. | 57 FR 5454; 2/14/92,<br>Fiche# OTS0540337,<br>Docket# OPPTS-44581 |
| 2-Ethylhexanol      | 104-76-7 | HECTOXCARC<br>Oncogenicity study                          | 40 CFR 798.3300<br>(modified)                             | rat                            | oral (gavage), 5 d/wk, 24 months            | 0, 50, 150, 500 mg/kg/d            | 50/sex           | Dose-related reduced body weight gain was noted at 150 mg/kg/day and higher, and clinical findings included poor general condition, labored breathing, and piloerection. Mortality occurred in females at 500 mg/kg/day. No evidence of oncogenicity was noted at any level.   | 57 FR 8454; 3/10/92,<br>Fiche# OTS0540339,<br>Docket# OPPTS-44581 |
| 2-Ethylhexanol      | 104-76-7 | HERTOXTERA<br>Developmental toxicity                      | Non-TSCA Protocol/<br>Guideline (see docket #OPTS-42087B) | rat                            | dermal, 6 hr/d, gestation days 6 through 15 | 0.3, 1.0, 3.0 mL/kg/d (neat)       | 25 mated females | Exposure by occluded dermal patch led to maternal toxicity (reduced weight gain) at the 3.0 mL/kg/day level, and exfoliation at the application site was seen at 1.0 mL/kg/day. No evidence of embryotoxicity, fetotoxicity, or teratogenicity were noted at any dose level. The NOAEL for maternal toxicity was 0.3 mL/kg/day, and for developmental toxicity, at least 3.0 mL/kg/day.  | 52 FR 27452; 7/21/87,<br>Fiche# OTS0530802                        |



## Results of Testing

| Chemical Name                   | CAS No.   | Study Code/Type               | Protocol/Guideline                                      | Species | Exposure   | Dose/Concentration                      | No. per Group             | Results  | Reference                                   |
|---------------------------------|-----------|-------------------------------|---|---------|--|---|---------------------------|--|---|
| Methyl <i>tert</i> -Butyl Ether | 1634-04-4 | HEADME Pharmacokinetics       | Non-TSCA Protocol/Guideline (see docket OPPTS # 42028D) | rats    | dermal, single exposure under occluded patch for 6 hours             | 40, 400 mg/kg                           | 60/sex                    | Maximum plasma concentrations were seen at 2 to 6 hours after the start of exposure. <i>tert</i> -Butyl alcohol was the major circulating metabolite, and peak concentrations were seen at 1 to 4 hr post dosing. Total plasma clearance was 389 to 458 mL/hour (low dose) and 273 to 364 mL/hour (high dose). The apparent volume of distribution was 0.60 to 3.9 (high and low dose, respectively).  | 55 FR 29411; 7/19/90<br>Fiche# OTS0528044   |
| Methyl <i>tert</i> -Butyl Ether | 1634-04-4 | HEADME Pharmacokinetics       | Non-TSCA Protocol/Guideline (see docket OPPTS # 42028D) | rats    | inhalation, nose-only;<br>a) single 6 hr or<br>b) 6 hr/d for 15 days | a) 0, 400, 8000 ppm or<br>b) 0, 400 ppm | a) 52/sex or<br>b) 40/sex | a) Steady-state plasma concentration was reached at 2 hours. Plasma elimination followed a one-compartment model. The elimination half-life was 0.52 and 0.63 hours for 400 and 8000 ppm exposures, respectively. The apparent volume of distribution was about 0.40 L and 0.52 L for low dose males and females, respectively, and 0.25 and 0.24 L for the high dose males and females, respectively. b) The plasma elimination half-life was 0.48 to 0.51 hours.   | 55 FR 29411; 7/19/90<br>Fiche# OTS0528044   |
| Methyl <i>tert</i> -Butyl Ether | 1634-04-4 | HEADME Pharmacokinetics       | Non-TSCA Protocol/Guideline (see docket OPPTS # 42028D) | rats    | oral (gavage), single dose   | 40, 400 mg/kg                           | 40/sex                    | Maximum plasma concentrations were seen at 15 minutes after dosing. <i>tert</i> -butyl alcohol was the major circulating metabolite, and peak concentrations were seen at 1 to 4 hours post-dosing. Total plasma clearance was 392 to 481 mL/hour (low-dose) and 287 to 358 mL/hour (high-dose) and the apparent volume distribution ranged from 0.27 to 0.43 L (high and low dose, respectively).   | 55 FR 29411; 7/19/90<br>Fiche# OTS0528044   |
| Methyl <i>tert</i> -Butyl Ether | 1634-04-4 | HECTOXCARC Oncogenicity study | 40 CFR 798.3300 (modified)                              | mice    | inhalation; 6 hr/day, 5 days/week, for 18 months                     | 0, 400, 3000, 8000 mg/kg                | 50/sex                    | An increased mortality rate and decreased mean survival time were observed only for male mice from the 8000 ppm group. At necropsy and upon microscopic examination, there were no exposure-related increases in nonneoplastic or neoplastic lesions in these organs except for the liver. At necropsy, an increase in the number of liver masses was observed from male and female mice from the 8000 ppm group. Upon microscopic evaluation, the only nonneoplastic lesion observed in the study was an increased incidence of hepatocellular hypertrophy noted for both sexes of mice from the 8000 ppm group and males from the 3000 ppm group. The only neoplastic lesion observed was an increased number of adenomas from female mice from the 8000 ppm group. The NOEL for toxic effects in mice was 400 ppm and the NOEL for oncogenicity effects in females was 3000 ppm and males was 8000 ppm. | 57 FR 5911; 12/14/91<br>Docket# OPPTS-44593 |
| Methyl <i>tert</i> -Butyl Ether | 1634-04-4 | HECTOXCARC Oncogenicity study | 40 CFR 798.3300 (modified)                              | rats    | inhalation; 6 hr/day, 5 days/week, for 24 months                     | 0, 400, 3000, 8000 mg/kg                | 50/sex                    | An increased mortality rate and decreased mean survival time were observed for male rats from the 3000 and 8000 ppm groups. The only neoplastic lesion noted was an increase in the number of adenomas and carcinomas in the kidneys of males rats exposed to 3000 or 8000 ppm. An increased incidence of nephropathy in male rats was observed even at the lowest concentration, thus, a NOEL could not be determined. However, the NOEL for oncogenicity effects in males was 400 ppm. The NOEL for toxic effects in females was 400 ppm and the NOEL for oncogenicity effects in females was greater than 8000 ppm.   | 57 FR 5911; 12/14/91<br>Docket# OPPTS-44593 |

## Results of Testing

| Chemical Name                   | CAS No.   | Study Code/Type  | Protocol/Guideline         | Species                        | Exposure   | Dose/Concentration                     | No. per Group             | Results  | Reference                                  |
|---------------------------------|-----------|--|----------------------------|--------------------------------|--|--|---------------------------|--|--|
| Methyl <i>tert</i> -Butyl Ether | 1634-04-4 | HEGTOXCHRM<br>Mammalian bone marrow chromosomal aberration assay | 40 CFR 798.5385 (modified) | rats                           | inhalation; 6 hr/d, 5 days   | 0, 800, 4000, 8000 ppm (target)        | 5/sex                     | No evidence of increased chromosomal aberrations was noted as compared to controls.  | 54 FR 25167; 6/13/89<br>Fiche# OTS0528040  |
| Methyl <i>tert</i> -Butyl Ether | 1634-04-4 | HEGTOXMUTA<br>Sex-linked recessive lethal assay                  | 40 CFR 798.5275 (modified) | <i>Drosophila melanogaster</i> | <i>in vivo</i> in sucrose solutions; 24 hr                             | 0, 0.03%, 0.15%, 0.3% solutions        | 50 males                  | Survival of high-, mid-, and low-exposure groups was 55.2, 76.8, and 86.0%, respectively. Solvent controls had 98.9% survivors. No evidence of mutagenicity was seen under these study conditions.   | 54 FR 21282; 5/17/89<br>Fiche# OTS0528039  |
| Methyl <i>tert</i> -Butyl Ether | 1634-04-4 | HENEUR<br>Motor activity   | 40 CFR 798.6200 (modified) | rats                           | inhalation; 6 hr/d, 5 d/wk, 13 wks                                     | 0, 797, 3920, 8043 ppm (mean measured) | 25/sex                    | Motor activity was decreased in males at 8043 ppm at week 8, only. Females exhibited increased activity at 3920 ppm (weeks 8 and 13).  | 54 FR 42034; 10/13/89<br>Fiche# OTS0528043 |
| Methyl <i>tert</i> -Butyl Ether | 1634-04-4 | HENEUR<br>Neuropathology study                                   | 40 CFR 798.6400 (modified) | rats                           | inhalation; 6 hr/d, 5 d/wk, 13 wks                                     | 0, 797, 3920, 8043 ppm (mean measured) | 25/sex                    | Absolute brain weight was decreased in the 8043 ppm group, but relative brain weight was not altered. No histopathological changes were seen in tissues of the peripheral or central nervous system.   | 54 FR 42034; 10/13/89<br>Fiche# OTS0528043 |
| Methyl <i>tert</i> -Butyl Ether | 1634-04-4 | HENEUR<br>Functional observational battery                       | 40 CFR 798.6050 (modified) | rats                           | inhalation; 6 hr/d, 5 d/wk, 13 wks                                     | 0, 797, 3920, 8043 ppm (mean measured) | 25/sex                    | Minor changes were noted at 3920 ppm and higher (e.g., elevated body temperature and decreased hind limb grip strength).   | 54 FR 42034; 10/13/89<br>Fiche# OTS0528043 |
| Methyl <i>tert</i> -Butyl Ether | 1634-04-4 | HERTOXTERA<br>Developmental toxicity                             | 40 CFR 798.4350 (modified) | mice                           | inhalation; 6 hr/d, gestation days 6-15                                | 0, 1000, 4000, 8000 ppm (target)       | 30 timed-pregnant females | Maternal toxicity was noted at 4000 ppm (reduced body weight and weight gain, hypoactivity, and ataxia), and at 8000 ppm, there were also prostration, labored respiration, lacrimation, and periocular encrustations. Reduced fetal body weight/litter and increased incidence of individual skeletal variations were noted in a treatment-related pattern at 4000 ppm and higher. The NOEL for both maternal and developmental toxicity was 1000 ppm.  | 54 FR 21117; 8/16/89<br>Fiche# OTS0528042  |
| Methyl <i>tert</i> -Butyl Ether | 1634-04-4 | HERTOXTERA<br>Developmental toxicity                             | 40 CFR 798.4350 (modified) | rabbits                        | inhalation; 6 hr/d, gestation days 6-18                                | 0, 1000, 4000, 8000 ppm (target)       | 15 timed-pregnant females | Maternal toxicity was observed at 4000 ppm and higher (reduced weight gain and food consumption) and at 8000 ppm, increased relative liver weight was seen. No evidence of embryotoxicity, fetotoxicity, or teratogenicity was observed at any exposure.   | 54 FR 21117; 8/4/89<br>Fiche# OTS0528041   |
| Methyl <i>tert</i> -Butyl Ether | 1634-04-4 | HERTOXTERE<br>Reproduction/fertility                             | 40 CFR 798.4700 (modified) | rats                           | inhalation; 10 wks pre-breeding, then continuous through 2 generations | 0, 400, 3000, 8000 ppm (target)        | 25/sex                    | Parental toxicity was noted at 3000 ppm and higher (lack of startle reflex and blepharospasm), but no treatment-related reproductive effects were observed in any treatment group. Fetotoxicity (decreased weight gain) was seen at 3000 ppm and higher. The NOEL for adults and offspring was 400 ppm.  | Fiche# OTS0534056                          |
| Methyl <i>tert</i> -Butyl Ether | 1634-04-4 | HESTOX<br>Subchronic toxicity                                    | 40 CFR 798.2450 (modified) | rats                           | inhalation; 6 hr/d, 5 d/wk, 13 wks                                     | 0, 797, 3920, 8043 ppm (mean measured) | 25/sex                    | Transient decreased body weight gain and food consumption was seen at 8043 ppm in both sexes, and in males at 3920 ppm. Mild hematologic and serum changes were seen at 8043 ppm. Concentration-related increased mean absolute and relative liver, kidney, and adrenal gland weights were noted at 797 (males) and 3920 (females) ppm and higher. Lymphoid hyperplasia in the nodes, marked hemosiderosis in the spleen, and larger hyaline droplets in the kidney of males were noted at 8000 ppm. | 54 FR 42034; 10/13/89<br>Fiche# OTS0528043 |

## Results of Testing

| Chemical Name                              | CAS No.  | Study Code/Type  | Protocol/Guideline                                      | Species      | Exposure  | Dose/Concentration  | No. per Group         | Results  | Reference                                 |
|--|----------|--|---|--------------|---|---|-----------------------|--|---|
| 1,4-Dichlorobenzene<br>( <i>para</i> -DCB) | 106-46-7 | HERTOXTERE<br>2-Generation<br>reproduction study               | 40 CFR 798.4700<br>(modified)                           | rat          | inhalation, 6 hr/d, 7<br>d/wk, 10 wks prior to<br>mating and during the<br>3-wk mating, gestation<br>(except females days<br>0-4), and lactation<br>periods | 0, 50, 150, 400 ppm   | 28/sex/group          | Adults from the F0 and F1 generation had decreased gestational body weight gain (females only), lactational body weight gain (F1 only) and litter size in the high-exposure groups. Males from the F0 and F1 generation had decreased brain and testes weight in the high-exposure group. Histopathological effects of the liver were observed in the high-exposure adults of the F0 and F1 generation. Histopathological effects of the kidney were observed in the adults of the F0 (high-exposure) and F1 (males at all exposure groups) generation. F1 (during lactation) and F2 pups from the high-exposure group had increased mortality rates and decreased body weights. | Fiche# OTS0523028                         |
| Chlorobenzene<br>(Monochloro-<br>benzene)  | 108-90-7 | HEGTOXDNAF<br>Unscheduled DNA<br>synthesis<br>(Voluntary test) | Non-TSCA Protocol/<br>Guideline (see docket<br>#47002F) | rat          | <i>in vitro</i>   | 10 <sup>-1</sup> , 10 <sup>-2</sup> , 10 <sup>-3</sup> , 10 <sup>-4</sup> ,<br>1.0% (v/v) | Not specified         | Chlorobenzene did not induce DNA repair at any concentration. Cytotoxicity was observed in cultures exposed to 10 <sup>-1</sup> to 1% of MCB. The test material was not genotoxic in this study.   | 49 FR 18779; 5/2/84<br>Fiche# OTS0511367  |
| Chlorobenzene<br>(Monochloro-<br>benzene)  | 108-90-7 | HERTOXTERE<br>2-Generation repro-<br>duction study             | 40 CFR 798.4700<br>(modified)                           | rat          | inhalation, 6 hr/d, 10<br>wks   | 50, 150, 450 ppm  | 30 male;<br>30 female | No mortality occurred among the control or treated test animals in either of the adult generations. In the low-dose group, no adverse effects of treatment were evident in the F <sub>0</sub> or F <sub>1</sub> generations. In the mid- and high-dose groups, mean liver weights were higher than the control, particularly in the males. Microscopic examination of the F <sub>0</sub> and F <sub>1</sub> adults revealed hepatocellular hypertrophy, renal degeneration, and inflammatory lesions (both male and female). Mid- and high-dose males exhibited an increased incidence of testicular degenerative changes (unilateral or bilateral).                             | 52 FR 2152; 1/20/87<br>Fiche# OTS0511472  |
| 1,2,4-Trichloro-<br>benzene                | 120-82-1 | EEATOX<br>Mysid shrimp acute<br>toxicity                       | 40 CFR 797.1930   | Mysid shrimp | 96 hr, flow-through   | 0.19, 0.28, 0.42, 0.60,<br>0.99 mg/L (measured)   | 20<br>(10/replicate)  | At the highest concentration, 100% mortality was observed for the test material 1,2,4-TCB. The LC <sub>50</sub> value (and 95% confidence limit) was 0.49 mg/L (0.43 to 0.56 mg/L). The no-observed-effect concentration was 0.19 mg/L.  | 53 FR 33537; 8/31/88<br>Fiche# OTS0523008 |
| 1,2,4-Trichloro-<br>benzene                | 120-82-1 | EECTOX<br>Mysid shrimp chronic<br>toxicity                     | 40 CFR 797.1950   | Mysid shrimp | 28 d, flow-through  | 0.013, 0.033, 0.064,<br>0.12, 0.28 mg/L<br>(measured)                                     | 60/<br>concentration  | Survival among high-dose F <sub>0</sub> animals exposed to 1,2,4-TCB was 32%, (which was significantly less than the survival of the F <sub>0</sub> test animals observed in the remaining 4 test concentrations). Concentration-related effects on growth (both generations) and reproduction (F <sup>0</sup> ) were noted. The MATC (based on reproduction) was estimated to be ≤ 0.064 mg/L and > 0.033 mg/L.   | 53 FR 33537; 8/31/88<br>Fiche# OTS0523008 |

## Results of Testing

| Chemical Name           | CAS No.  | Study Code/Type  | Protocol/Guideline                                      | Species                | Exposure            | Dose/Concentration  | No. per Group        | Results   | Reference                                     |
|-------------------------|----------|--|---|------------------------|---------------------|---|----------------------|---|---|
| 1,2,4-Trichloro-benzene | 120-82-1 | HECTOXCARC<br>Oncogenicity study                               | 40 CFR 798.3300<br>(modified)                           | rat                    | diet, 104 weeks     | 100, 350, 1200 ppm  | 50/sex               | The 1200 ppm dietary concentration produced significant decrease in survival of the males at week 104, hepatocellular hypertrophy, diffuse fatty change in the liver, hepatic focal cystic degeneration, significantly increased mean absolute liver weight and mean liver-to-terminal-body-weight ratio, and significantly increased mean liver-to-brain-weight ratio in males. Findings at necropsy included enlarged livers, transitional cell hyperplasia of the renal pelvic urothelium, and chronic progressive nephropathy in males in the 1200 ppm group. Renal pelvis mineralization and granular, pitted, and rough appearance of the kidneys were observed in males and females in the 1200 ppm group. The 100 and 350 ppm dietary concentrations produced no treatment-related effects. The NOEL for systemic toxicity was 350 ppm. | 59 FR 38472; 7/28/94,<br>Docket# OPPTS-44612  |
| 1,2,4-Trichloro-benzene | 120-82-1 | HECTOXCARC<br>Oncogenicity study                               | 40 CFR 798.3300<br>(modified)                           | mouse                  | diet, 104 weeks     | 150, 700, 3200 ppm  | 50/sex               | Dietary concentrations of 150, 700, and 3200 ppm produced treatment-related effects such as distended abdomen and increased mean liver weight. Liver masses, hepatocellular carcinomas, hepatocellular adenomas, and centrilobular hepatocytomegaly were evident in animals treated in the 700 and 3200 ppm groups. A significant decrease in survival at week 104 was observed in the 3200 ppm group; no females survived to study termination in the 3200 ppm group.  | 59 FR 38472; 7/28/94,<br>Docket# OPPTS-44612  |
| 1,2,4-Trichloro-benzene | 120-82-1 | HEGTOXDNAF<br>Unscheduled DNA<br>synthesis<br>(Voluntary test) | Non-TSCA Protocol/<br>Guideline (see docket<br>#47002F) | rat                    | <i>in vitro</i>     | 10 <sup>-1</sup> , 10 <sup>-2</sup> , 10 <sup>-3</sup> , 10 <sup>-4</sup> ,<br>1.0% (v/v) | Not specified        | 1,2,4-Trichlorobenzene did not induce DNA repair at any concentration. Cytotoxicity was observed in cultures exposed to 10 <sup>-2</sup> to 1% of TCB. The test material was not genotoxic in this study.   | 49 FR 18779; 5/2/84<br>Fiche# OTS0511367      |
| 1,2,3-Trichloro-benzene | 87-61-6  | EEATOX<br>Mysid shrimp acute<br>toxicity                       | 40 CFR 797.1930   | Mysid shrimp           | 96 hr, flow-through | 0.12, 0.13, 0.21, 0.35,<br>0.57 mg/L (measured)   | 20<br>(10/replicate) | Of the test animals exposed to 0.57 mg/L of test material (1,2,3-TCB), only 15% survived. The LC <sub>50</sub> value (and 95% confidence interval) was 0.35 mg/L (0.30 to 0.42 mg/L). The no-observed-effect concentrations was 0.21 mg/L.  | 53 FR 33537; 8/31/88<br>Fiche# OTS0523008     |
| 1,2,3-Trichloro-benzene | 87-61-6  | EEATOX<br>Acute fish toxicity                                  | 40 CFR 797.1400   | Atlantic<br>silverside | 96 hr, flow-through | 0.53, 0.83, 1.3, 1.9, 2.8<br>mg/L (measured)  | 20<br>(10/replicate) | At the 2 highest test concentrations of 1,2,3-trichlorobenzene (1,2,3-TCB), 100% mortality was observed, and 25% mortality was noted at 1.3 mg/L. The remaining concentration produced 0% mortality. The LC <sub>50</sub> value (and 95% confidence level) was 1.4 mg/L (1.3 to 1.9 mg/L). The no-observed-effect concentration was less than 0.53 mg/L.  | 53 FR 33537; 8/31/88<br>Fiche# OTS0523008     |
| 1,2,3-Trichloro-benzene | 87-61-6  | EEATOX<br>Acute fish toxicity                                  | 40 CFR 797.1400   | Fathead<br>minnow      | 96 hr, flow-through | 0.069, 0.96, 1.5, 2.2, 3.5<br>mg/L (measured)   | 20<br>(10/replicate) | Total mortality was observed at the highest concentration of the test material, 1,2,3-trichlorobenzene, and 30% mortality at the 2.2 mg/L level. The remaining concentrations had 0% mortality. The LC <sub>50</sub> value (and 95% confidence interval) was 2.4 mg/L (1.5 to 3.5 mg/L). The no-observed-effect concentration was 0.69 mg/L.  | 53 FR 33537; 8/31/88<br>Fiche# OTS0523008     |
| 1,2,3-Trichloro-benzene | 87-61-6  | EEATOX<br>Acute aquatic toxicity,<br>crustacean                | 40 CFR 797.1310   | Gammarids              | 96 hr, flow-through | 0.31, 0.47, 0.60, 1.0, 1.4<br>mg/L (measured)   | 20<br>(10/replicate) | At 96 hours, 100% mortality was observed in the highest test concentration of 1,2,3-TCB (1.4 mg/L). Mortality in the remaining treatment levels ranged from 0 to 25%. Lethargy was observed at all concentrations. The LC <sub>50</sub> value (and 95% confidence limit) were 1.1 mg/L (1.0 to 1.4 mg/L).   | 53 FR 43267;<br>10/26/88<br>Fiche# OTS0523009 |

## Results of Testing

| Chemical Name                             | CAS No. | Study Code/Type  | Protocol/Guideline                                   | Species        | Exposure  | Dose/Concentration   | No. per Group                          | Results  | Reference                                 |
|---|---------|--|--|----------------|---|--|--|--|---|
| 1,2,3-Trichloro-benzene                   | 87-61-6 | EECTOX<br>Mysid shrimp chronic toxicity                  | 40 CFR 797.1950                                      | Mysid shrimp   | 28 d, flow-through  | 0.017 - 0.26 mg/L (measured)   | 60/<br>concentration<br>(30/replicate) | No effects on survival of the parent generation were seen at any test concentration. Reproduction was totally inhibited at the high concentration.   | 53 FR 49227; 12/6/88<br>Fiche# OTS0523010 |
| 1,2-Dichloro-benzene ( <i>ortho</i> -DCB) | 95-50-1 | EFADEGHYDR<br>Hydrolysis study                           | Non-TSCA Protocol/<br>Guideline (see docket #47002F) | Not applicable | pH 3, 7, 11; 25 °C  | Not specified  | Not applicable                         | Rate constants of 1,2-dichlorobenzene for pH 3, 7, and 11 were 0.0195, 0.0196, and 0.0153/day, respectively; half-lives at the same pH levels were 35.5, 35.4, and 45.4 days, respectively.  | 54 FR 21282; 5/17/89<br>Fiche# OTS0526333 |
| 1,2-Dichlorobenzene ( <i>ortho</i> -DCB)  | 95-50-1 | HEGTOXDNAF<br>Unscheduled DNA synthesis (Voluntary test) | Non-TSCA Protocol/<br>Guideline (see docket #47002F) | rat            | <i>in vitro</i>   | 10 <sup>-1</sup> , 10 <sup>-2</sup> , 10 <sup>-3</sup> , 10 <sup>-4</sup> , 1.0% (v/v) | Not specified                          | 1,2-Dichlorobenzene did not induce DNA repair at any concentration. Cytotoxicity was observed in cultures exposed to 10 <sup>-2</sup> to 1% of DCB. The test material was not genotoxic in this study.   | 49 FR 18779; 5/2/84<br>Fiche# OTS0511367  |
| 1,2-Dichlorobenzene ( <i>ortho</i> -DCB)  | 95-50-1 | HERTOXTERE<br>2-Generation reproduction study            | 40 CFR 798.4700 (modified))                          | rat            | inhalation, 6 hr/d, 7 d/wk, 10 wks prior to mating and during the 3-wk mating, gestation (except females days 0-4), and lactation periods | 0, 50, 150, 400 ppm  | 30/sex/group                           | Histopathological effects were observed in the F0 and F1 generation in the liver (mid- and high exposure male and females) and kidney (mid- and high exposure males). No adverse effects were observed in any treated rat with respect to reproductive performance, fertility indices, gestational or lactation weight gain, litter size, or pup survival indices.   | Fiche# OTS0523028                         |
| 1,2,4,5-Tetrachloro-benzene               | 95-94-3 | EFADEGHYDR<br>Hydrolysis study                           | Non-TSCA Protocol/<br>Guideline (see docket #42050A) | Not applicable | pH 3, 7, 11; 25 °C  | Not specified  | Not applicable                         | The rate constants of 1,2,4,5-tetrachlorobenzene for pH 3, 7, and 11 were 0.0157, 0.0142, and 0.0165/day, respectively; half-lives at the same pH levels were 44.2, 48.9, and 42.days, respectively.   | 54 FR 21282; 5/17/89<br>Fiche# OTS0526333 |
| 1,2,4,5-Tetrachloro-benzene               | 95-94-3 | HERTOXTERA<br>Developmental toxicity                     | 40 CFR 798.4900 (modified)                           | rat            | oral (gavage), gestation days 6-15  | 0, 25, 75, 125 mg/kg/d   | 25 mated females                       | Maternal toxicity (increased relative liver weight) was noted at 75 mg/kg/day, and decreased body weight gain and food intake at 125 mg/kg/day. Fetotoxicity (increased skeletal variations) occurred at all dose levels. No embryotoxicity or teratogenicity was noted at any treatment level. The maternal NOEL was 25 mg/kg/day.  | 53 FR 951; 1/14/88<br>Fiche# OTS0523027   |
| 1,2,4,5-Tetrachloro-benzene               | 95-94-3 | HERTOXTERA<br>Developmental toxicity                     | 40 CFR 798.4900 (modified)                           | rabbit         | oral (gavage), gestation days 6-18  | 0, 5, 15, 25 mg/kg/d   | 15 bred females                        | Maternal toxicity (death; reduced body weight gain) occurred at all doses. Increased visceral and skeletal variations were noted at low and mid-dose levels. The NOEL for maternal and developmental toxicity was <5 mg/kg/day.  | 53 FR 951; 1/14/88<br>Fiche# OTS0523027   |
| 1,2,4,5-Tetrachloro-benzene               | 95-94-3 | HERTOXTERE<br>2-Generation reproduction study            | 40 CFR 798.4700 (modified))                          | rat            | 10 wks, oral (dietary)  | 0, 30, 300, 1000 ppm   | 28 male;<br>28 female                  | Adult F <sub>0</sub> males exhibited reduced body weights, weight gains, and food consumption at 1000 ppm. F <sub>0</sub> males (1000 ppm) exhibited a significant increase in liver and kidney size as well as color changes in the lymph nodes. Females at the same dose level had color changes in the jejunum. Adult females (F <sub>0</sub> ) at 30 and 300 ppm exhibited occasional weight reductions. There were significant reductions in maternal gestational and lactational body weights at the high-dose level. The number of F <sub>1</sub> stillborn and postnatal deaths was increased at 300 and 1000 ppm. | 54 FR 21282; 5/17/89<br>Fiche# OTS0523029 |

## Results of Testing

| Chemical Name                        | CAS No.    | Study Code/Type                               | Protocol/Guideline                                      | Species                                 | Exposure                                   | Dose/Concentration     | No. per Group         | Results  | Reference  |
|--------------------------------------|------------|---|---|---|--|------------------------|-----------------------|--|--|
| C <sub>9</sub> Aromatic Hydrocarbons | 70693-06-0 | HEGTOXCHRM<br>Mammalian<br>cytogenetic study  | Non-TSCA Protocol/<br>Guideline (see docket<br>#42034D) | rat bone marrow<br>cells                | inhalation, 6 hr/d; 5 d                    | 153, 471, 1540 ppm     | 15 male;<br>15 female | An exposure level 1540 ppm of test material produced decreases in absolute body weights and body weight gains. There were no other signs of toxicity in any of the exposed test animals. The test material did not induce chromosomal aberrations.   | 53 FR 6198; 3/1/88<br>Fiche# OTS0515092                                |
| C <sub>9</sub> Aromatic Hydrocarbons | 70693-06-0 | HEGTOXCHRM<br>Chromosomal<br>aberrations      | Non-TSCA Protocol/<br>Guideline (see docket<br>#42034D) | Chinese<br>hamster ovaries<br>(CHO)     | <i>in vitro</i>                            | 15.0-150 µg/mL         | Not specified         | There were no significant increases in chromosomal aberrations at any of the concentrations tested up to levels of cytotoxicity, with or without activation.   | 53 FR 6198; 3/1/88<br>Fiche# OTS0515092                                |
| C <sub>9</sub> Aromatic Hydrocarbons | 70693-06-0 | HEGTOXDNAF<br>Sister chromatid<br>exchange    | Non-TSCA Protocol/<br>Guideline (see docket<br>#42034D) | Chinese<br>hamster ovaries<br>(CHO)     | <i>in vitro</i>                            | 0.0667-2000 µg/mL      | Not specified         | There were no significant increases in sister chromatid exchange at the concentrations tested.   | 53 FR 6198; 3/1/88<br>Fiche# OTS0515092                                |
| C <sub>9</sub> Aromatic Hydrocarbons | 70693-06-0 | HEGTOXMUTA<br>Gene mutation<br>(CHO/HGPRT)    | Non-TSCA Protocol/<br>Guideline (see docket<br>#42034D) | Chinese<br>hamster ovaries              | <i>in vitro</i>                            | 0.01-0.20 µL/mL        | Not specified         | No dose-related or toxicity-related increases in mutant frequencies were observed, with or without activation.   | 53 FR 6198; 3/1/88<br>Fiche# OTS0515092                                |
| C <sub>9</sub> Aromatic Hydrocarbons | 70693-06-0 | HEGTOXMUTA<br>Mutagenicity study              | Non-TSCA Protocol/<br>Guideline (see docket<br>#42034D) | <i>Salmonella</i><br><i>typhimurium</i> | <i>in vitro</i>                            | 0.0025-0.5000 µL/plate | Not applicable        | The test strains used were TA98, TA100, TA1535, TA1537, and TA1538. The test material did not exhibit any genetic activity in these assays under the test conditions, with or without activation.  | 53 FR 6198; 3/1/88<br>Fiche# OTS0515092                                |
| C <sub>9</sub> Aromatic Hydrocarbons | 70693-06-0 | HENEUR<br>Neuropathology study                | Non-TSCA Protocol/<br>Guideline (see docket<br>#42034D) | rats                                    | inhalation, 6 hr/d;<br>5 d/wk, 13 wks      | 101, 452, 1320 ppm     | 40 males              | Examination of sections of brain, cervical and lumbar spinal cord, and left and right proximal sciatic nerves failed to reveal any neurotoxic changes.   | 53 FR 23450; 6/22/88<br>Fiche# OTS0515091                              |
| C <sub>9</sub> Aromatic Hydrocarbons | 70693-06-0 | HENEUR<br>Motor activity assay                | Non-TSCA Protocol/<br>Guideline (see docket<br>#42034D) | rats                                    | inhalation, 6 hr/d;<br>5 d/wk, 13 wks      | 101, 452, 1320 ppm     | 20 male               | No effects were noted on motor activity at any treatment level.  | 53 FR 23450; 6/22/88<br>Fiche# OTS0515091                              |
| C <sub>9</sub> Aromatic Hydrocarbons | 70693-06-0 | HENEUR<br>Functional<br>observational battery | Non-TSCA Protocol/<br>Guideline (see docket<br>#42034D) | rats                                    | inhalation, 6 hr/d;<br>5 d/wk, 13 wks      | 101, 452, 1320 ppm     | 20 male               | Body weight was depressed in the high-dose group by about 13% during the exposure period. No effects were noted on startle response, forelimb and hind limb grip strength, hind limb splay, or thermal response.   | 53 FR 23450; 6/22/88<br>Fiche# OTS0515091                              |
| C <sub>9</sub> Aromatic Hydrocarbons | 70693-06-0 | HERTOXTERA<br>Developmental<br>toxicity       | Non-TSCA Protocol/<br>Guideline (see docket<br>#42034D) | mice                                    | inhalation, 6 hr/d,<br>gestation days 6-15 | 100, 500, 1500 ppm     | 30                    | Developmental toxicity was observed at the 500 and 1500 ppm dose levels. This was manifested as a significant increase in mean postimplantation loss at 1500 ppm, and significant decreases in mean fetal body weights at 500 and 1500 ppm levels. Adverse effects on fetal development also included increased incidence of unossified sternebrae and reduced skull ossification at 1500 ppm as compared to controls. Maternal toxicity included near 50% mortality, reduced food intake and inhibited body weight gain during exposure and overall gestation period and significant decreases in mean hemotocrit and mean corpuscular hemoglobin concentration at 1500 ppm. The NOEL for developmental toxicity was 100 ppm. | 53 FR 27564; 7/21/88,<br>Fiche# OTS0532926,<br>Docket# OPPTS-<br>44513 |

## Results of Testing

| Chemical Name                        | CAS No.    | Study Code/Type                               | Protocol/Guideline                                       | Species     | Exposure              | Dose/Concentration | No. per Group | Results  | Reference   |
|--------------------------------------|------------|---|--|-------------|-----------------------|--------------------|---------------|--|---|
| C <sub>9</sub> Aromatic Hydrocarbons | 70693-06-0 | HERTOXTERE 3-Generation reproductive toxicity | Non-TSCA Protocol/ Guideline (see docket #42034D)        | rat         | inhalation, 10-12 wks | 103, 495, 1480 ppm | 30/sex        | Animals in the F <sub>0</sub> and F <sub>1</sub> generations were exposed for 10 weeks prior to mating. Exposure of animals in the F <sub>2</sub> generation was initiated on postnatal day 22 and was continued for 10-12 weeks prior to mating. The NOEL with respect to reproductive effects across the generations was 495 ppm. Under an exposure regimen where the animals were at least 5 weeks old at the time of the initial exposure (F <sub>0</sub> and F <sub>1</sub> generations), offspring growth and development were also unaffected at the 495 ppm level. The NOEL with respect to F <sub>0</sub> and F <sub>1</sub> parental systemic toxicity was 103 ppm. In the F <sub>2</sub> generation, exposure was initiated in animals about 3 weeks of age and the younger animals were clearly more susceptible to C <sub>9</sub> hydrocarbon exposure than more mature animals. The net effect was an effective lowering of the NOEL for offspring growth was 103 ppm. Parental toxicity, in the terms of an inhibition of body weight and food consumption, was present at all dosage levels. | 54 FR 36050; 8/31/89, Fiche# OTS053927, Docket# OPPTS-44536 |
| Acrylic Acid                         | 79-10-7    | HEADME Bioavailability assay                  | Non-TSCA Protocol/ Guideline (see docket OPPTS # 42146A) | mice (male) | intravenous           | 10 mg/kg           | 15            | Four hours after dosing, 33.51% of the dose had been exhaled as CO <sub>2</sub> ; an additional 17.48% was exhaled by 72 hours. By 72 hours, 2.12% of the dose was recovered in urine, 0.71% in the feces, 0.83% in the carcass, and 0.16% in tissues (0.004%, 0.136%, 0.015%, and 0.007% in plasma, liver, kidney, and fat, respectively) ; 44.3% of the administered dose was not recovered.   | 59 FR 4069; 1/28/94, Docket# OPPTS-44605                    |
| Acrylic Acid                         | 79-10-7    | HEADME Bioavailability assay                  | Non-TSCA Protocol/ Guideline (see docket OPPTS # 42146A) | mice (male) | oral                  | 40, 150 mg/kg      | 15            | Four hours after the 40-mg/kg dose, 53.07% of the dose had been exhaled as CO <sub>2</sub> ; an additional 23.71% was exhaled by 72 hours. By 72 hours, 2.96% of the dose was recovered in urine, 1.21% in the feces, 0.76% in the carcass, and 0.26% in tissues (0.006%, 0.129%, 0.061%, 0.001%, 0.068%, and 0.003% in plasma, liver, kidney, fat, stomach, and stomach contents, respectively) ; 17.51% of the administered dose was not recovered. Four hours after the 150-mg/kg dose, 57.8% of the dose had been exhaled as CO <sub>2</sub> ; an additional 22.24% was exhaled by 72 hours. By 72 hours, 3.4% of the dose was recovered in urine, 1.18% in the feces, 0.28% in the carcass, and 0.08% in tissues (0.003%, 0.051%, 0.017%, 0.001%, 0.031%, and 0.004% in plasma, liver, kidney, fat, stomach, and stomach contents, respectively); 13.07% of the administered dose was not recovered.  | 59 FR 4069; 1/28/94, Docket# OPPTS-44605                    |

## Results of Testing

| Chemical Name | CAS No. | Study Code/Type                 | Protocol/Guideline   | Species     | Exposure    | Dose/Concentration | No. per Group | Results   | Reference                                       |
|---------------|---------|---------------------------------|--|-------------|-------------|--------------------|---------------|---|---|
| Acrylic Acid  | 79-10-7 | HEADME<br>Bioavailability assay | Non-TSCA Protocol/<br>Guideline (see docket<br>OPPTS # 42146A) | mice (male) | dermal      | 10, 40 mg/kg       | 15            | Twenty-four hours after the 10-mg/kg dose, 7.58% of the dose had been exhaled as CO <sub>2</sub> ; an additional 1.76% was exhaled by 72 hours. By 72 hours, 0.34% of the dose was recovered in urine, 0.4% in the feces, 0.49% in the carcass, and 0.18% in tissues (0.002, 0.098%, 0.072%, and 0.015% in plasma, liver, kidney, and fat, respectively); an additional 73% was recovered as volatiles, in occlusion devices, and on the skin. 16% of the administered dose was not recovered. Twenty-four hours after the 40-mg/kg dose, 8.43% of the dose had been exhaled as CO <sub>2</sub> ; an additional 1.16% was exhaled by 72 hours. By 72 hours, 0.44% of the dose was recovered in urine, 0.2% in the feces, 0.77% in the carcass, and 0.03% in tissues (0.029%, 0.004%, and 0.001% in liver, kidney, and fat, respectively); an additional 50.28% was recovered as volatiles, in occlusion devices, and on the skin. 38.5% of the administered dose was not recovered. | 59 FR 4069; 1/28/94,<br>Docket# OPPTS-<br>44605 |
| Acrylic Acid  | 79-10-7 | HEADME<br>Bioavailability assay | Non-TSCA Protocol/<br>Guideline (see docket<br>OPPTS # 42146A) | rats (male) | intravenous | 10 mg/kg           | 15            | Four hours after dosing, 63.2% of the dose had been exhaled as CO <sub>2</sub> ; an additional 5.24% was exhaled by 72 hours. By 72 hours, 2.9% of the dose was recovered in urine, 0.69% in the feces, 0.56% in the carcass, and 0.18% in tissues (0.001%, 0.149%, 0.027%, and 0.005% in plasma, liver, kidney, and fat, respectively) ; 27.2% of the administered dose was not recovered.   | 59 FR 4069; 1/28/94,<br>Docket# OPPTS-<br>44605 |
| Acrylic Acid  | 79-10-7 | HEADME<br>Bioavailability assay | Non-TSCA Protocol/<br>Guideline (see docket<br>OPPTS # 42146A) | rats (male) | oral        | 40, 150 mg/kg      | 15            | Four hours after the 40-mg/kg dose, 53.07% of the dose had been exhaled as CO <sub>2</sub> ; an additional 23.71% was exhaled by 72 hours. By 72 hours, 2.96% of the dose was recovered in urine, 1.21% in the feces, 0.76% in the carcass, and 0.26% in tissues (0.006%, 0.129%, 0.061%, 0.001%, 0.068%, and 0.003% in plasma, liver, kidney, fat, stomach, and stomach contents, respectively) ; 17.51% of the administered dose was not recovered. Four hours after the 150-mg/kg dose, 57.8% of the dose had been exhaled as CO <sub>2</sub> ; an additional 22.24% was exhaled by 72 hours. By 72 hours, 3.4% of the dose was recovered in urine, 1.18% in the feces, 0.28% in the carcass, and 0.08% in tissues (0.003%, 0.051%, 0.017%, 0.001%, 0.031%, and 0.004% in plasma, liver, kidney, fat, stomach, and stomach contents, respectively); 13.07% of the administered dose was not recovered.   | 59 FR 4069; 1/28/94,<br>Docket# OPPTS-<br>44605 |



## Results of Testing

| Chemical Name  | CAS No.  | Study Code/Type                                | Protocol/Guideline   | Species                       | Exposure                      | Dose/Concentration               | No. per Group                    | Results   | Reference  |
|----------------|----------|--|--|-------------------------------|-------------------------------|----------------------------------|----------------------------------|---|--|
| Acrylic Acid   | 79-10-7  | HEADME<br>Bioavailability assay                | Non-TSCA Protocol/<br>Guideline (see docket<br>OPPTS # 42146A) | rats (male)                   | dermal                        | 10, 40 mg/kg                     | 15                               | Twenty-four hours after the 10-mg/kg dose, 11.11% of the dose had been exhaled as CO <sub>2</sub> ; an additional 2.38% was exhaled by 72 hours. By 72 hours, 0.82% of the dose was recovered in urine, 0.49% in the feces, 2.77% in the carcass, and 0.24% in tissues (0.171%, 0.046%, and 0.018% in liver, kidney, and fat, respectively); an additional 43.08% was recovered as volatiles, in occlusion devices, and on the skin. 38.9% of the administered dose was not recovered. Twenty-four hours after the 40-mg/kg dose, 17.62% of the dose had been exhaled as CO <sub>2</sub> ; an additional 2.11% was exhaled by 72 hours. By 72 hours, 1.96% of the dose was recovered in urine, 0.75% in the feces, 1.66% in the carcass, and 0.05% in tissues (0.039%, 0.006%, and 0.005% in liver, kidney, and fat, respectively); an additional 27.61% was recovered as volatiles, in occlusion devices, and on the skin. 47.8% of the administered dose was not recovered. | 59 FR 4069; 1/28/94,<br>Docket# OPPTS-<br>44605  |
| Acrylic Acid   | 79-10-7  | HERTOXTERA<br>Developmental<br>toxicity        | 40 CFR 798.4350<br>(modified)                                  | rabbits                       | inhalation, 6hr/d, 13<br>days | 25, 75, 225 ppm                  | 16 timed-<br>pregnant<br>females | No females aborted, delivered early, or were removed from the study. No mortality occurred during the study. The overall pregnancy rate ranged from 94 to 100%. All pregnant females bore viable fetuses. Clinical signs included perinatal and/or perioral wetness and nasal congestion at 225 and 75 ppm. Blepharospasm was observed at 225 ppm. Ulceration of the nasal turbinates was observed in a single doe at 225 ppm. There was no evidence of developmental toxicity, including teratogenicity, at any exposure concentration. The NOEL for maternal toxicity was 25 ppm. The NOEL for developmental effects was at least 225 ppm.  | 58 FR 40427;<br>7/28/93, Docket#<br>OPPTS-44600  |
| Acrylic Acid   | 79-10-7  | HERTOXTERE<br>Reproduction/<br>fertility assay | 40 CFR 798.4700<br>(modified)                                  | rats                          | oral (drinking water)         | 0, 500, 2500, 5000<br>ppm        | 25 male;<br>25 female            | Preliminary results indicate that at 5000 ppm, body weights and/or body weight gain of the F0 males and females were slightly lower than controls. At 5000 ppm, drinking water consumption was also decreased in both male and females. At 5000 ppm, statistically significantly lower mean pup body weights and decreased weight gains of the males and female F1 pups was observed from day 14 to day 21 of the weaning period. At 2500 ppm, there were no indications of parental toxicity from the parameters evaluated. At ,5000 ppm, slight decreases in pup body weight and pup body weight gains were noted on day 21 after birth. At 500 ppm, no substance-induced findings on F0 parental animals or F1 pups occurred.  | 59 FR 17101;<br>4/11/94<br>Fiche# OTS0538285     |
| Sodium Cyanide | 143-33-9 | EEATOX<br>Avian dietary test                   | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-<br>42118) | bobwhite                      | oral, 5 days                  | 100, 178, 316, 562,<br>1000 mg/L | 10                               | The LD <sub>50</sub> value for the bobwhite was determined to be 705 mg/L. The no mortality concentration was 316 mg/L and the NOEL was 100 mg/L.   | 58 FR 48366; 9/15/93,<br>Docket# OPPTS-<br>44601 |
| Sodium Cyanide | 143-33-9 | EEATOX<br>Avian dietary test                   | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-<br>42118) | bobwhite and<br>mallard ducks | oral, 5 days                  | 100, 178, 316, 562,<br>1000 mg/L | 10                               | The LD <sub>50</sub> value was determined to be 340 mg/L. The no mortality concentration was 178 mg/L and the NOEL was < 100 mg/L.  | 58 FR 48366; 9/15/93,<br>Docket# OPPTS-<br>44601 |

## Results of Testing

| Chemical Name         | CAS No.  | Study Code/Type                                   | Protocol/Guideline                                     | Species                  | Exposure                            | Dose/Concentration               | No. per Group            | Results  | Reference                                  |
|-----------------------|----------|---|--|--------------------------|-------------------------------------|----------------------------------|--------------------------|--|--|
| Sodium Cyanide        | 143-33-9 | EFBIOC<br>Plant uptake and translocation          | 40 CFR 797.2850  | Alkali sacaton           | irrigation, in sand, growth chamber | Sodium cyanide in water, pH 10.5 | 80 seeds per pot; 3 pots | Poor germination; mortality greater than 50% after two months with evidence of chlorosis and or necrosis.  | received 12/27/94, docket #OPPTS 42118     |
| Sodium Cyanide        | 143-33-9 | EFBIOC<br>Plant uptake and translocation          | 40 CFR 797.2850  | <i>Larrea tridentata</i> | irrigation, in sand, growth chamber | Sodium cyanide in water, pH 10.5 | 80 seeds per pot; 3 pots | Poor germination; mortality of 50% in 3 months and 80% mortality in 6 months with most developing chlorosis and or necrosis.   | received 12/27/94, docket #OPPTS 42118     |
| Sodium Cyanide        | 143-33-9 | EFTSPT<br>Soil and sediment adsorption            | 40 CFR 796.2750  | Not applicable           | Not applicable                      | Not applicable                   | Not applicable           | The Freundlich plot of the absorption isotherm data resulted in values for the empirical constants 2/n and log K <sub>f</sub> of 0.636 and 1.30, respectively. The distribution coefficients (K <sub>d</sub> ), in terms of equilibrium concentrations, ranged from 5.04 to 14.5. The effects of metal chelation and/or biotransformation were not considered in the quantitation and calculations. Excluding these mechanisms, the data suggest CN <sup>-</sup> is tightly bound to soil and hence immobile | 58 FR 40427; 7/28/93, Docket# OPPTS-44600  |
| 1,1,1-Trichloroethane | 71-55-6  | HECTOXCARC<br>Oncogenicity (Voluntary test)       | Non-TSCA Protocol/Guideline                            | rats                     | inhalation, 6 hr/d, 5 d/wk, 2 yrs   | 0, 150, 500, 1500 ppm            | 80/sex/group             | Hematology, urinalysis, and clinical chemistry findings were unaffected by treatment. Microscopic findings of the livers of rats exposed to 1500 ppm revealed an accentuation of the normal hepatic lobular pattern consisting of altered cytoplasmic staining in the cells surrounding the central vein.  | 51 FR 27598; 8/1/86<br>Fiche# OTS0510656   |
| 1,1,1-Trichloroethane | 71-55-6  | HEGTOXCHRM<br>Mouse bone marrow micronucleus test | Non-TSCA Protocol/Guideline (see docket # OPTS-42059E) | mice                     | inhalation, in vivo, 6 hr           | 0, 1700, 4300, 6800 ppm          | 5/sex                    | No evidence of increased clastogenicity was observed.  | 55 FR 50055; 12/04/90<br>Fiche# OTS0533133 |
| 1,1,1-Trichloroethane | 71-55-6  | HENEUR<br>Functional observational battery        | Non-TSCA Protocol/Guideline (see docket # OPTS-42059E) | rats                     | inhalation, 6 hr/d, 5 d/wk, 13 wks  | 0, 200, 630, 2000 ppm            | 14/sex                   | No treatment related findings were seen except that a slightly smaller forelimb grip performance was reported in the 2000 ppm group.   | 56 FR 5688; 2/12/91<br>Fiche# OTS0533136   |
| 1,1,1-Trichloroethane | 71-55-6  | HENEUR<br>Motor activity                          | Non-TSCA Protocol/Guideline (see docket # OPTS-42059E) | rats                     | inhalation, 6 hr/d, 4 days          | 4000 ppm                         | Not specified            | Decreased activity occurred in males and females after the 1st day's exposure. Day 4 data showed slightly increased motor activity among males and slightly decreased activity among females.  | 56 FR 5688; 1/12/91<br>Fiche# OTS0533134   |
| 1,1,1-Trichloroethane | 71-55-6  | HENEUR<br>Neuropathology                          | Non-TSCA Protocol/Guideline (see docket # OPTS-42059E) | rats                     | inhalation, 6 hr/d, 5 d/wk, 13 wks  | 0, 200, 630, 2000 ppm            | 14/sex                   | Histopathologic examination of the brain, spinal cord, peripheral nerves, and limb muscles revealed no effects from exposure.  | 56 FR 28893; 6/25/91<br>Fiche# OTS0533136  |
| 1,1,1-Trichloroethane | 71-55-6  | HENEUR<br>Sensory evoked potential battery        | Non-TSCA Protocol/Guideline (see docket # OPTS-42059E) | rats                     | inhalation, 6 hr/d, 4 days          | 0, 1000, 2000 ppm                | 10 females               | Tests after exposure on day 4 revealed altered large flash evoked potential and electroencephalogram and slowed high frequency components of the somatosensory evoked potential in rats at 2000 ppm; smaller changes in evoked potential and eeg were seen at 1000 ppm.  | 56 FR 28893; 6/25/91<br>Fiche# OTS0533134  |

## Results of Testing

| Chemical Name          | CAS No.  | Study Code/Type                          | Protocol/Guideline  | Species | Exposure                                   | Dose/Concentration         | No. per Group                            | Results  | Reference  |
|------------------------|----------|--|---|---------|--|----------------------------|--|--|--|
| 1,1,1-Trichloro-ethane | 71-55-6  | HENEUR<br>Developmental<br>neurotoxicity | Non-TSCA<br>Protocol/Guideline<br>(see docket #<br>OPTS-42059E) | rats    | gavage, gestation day 6<br>- lation day 10 | 75, 250, 750 mg/kg         | 4/sex                                    | There were no effects attributed to treatment on maturational landmarks. Statistically significant decreases in pup weights were noted, but not considered biologically significant. No treatment-related effects were seen in any of the FOB parameters. Motor activity was not affected either in pups tested in the neonatal or young adult stage. There were no observed neurologic lesions and no brain measurement differences attributable to treatment in rats at 28 or 62 days of age. Finally, the test substance did not have any effects on short-term memory, learning, or performance. | 58 FR 40427; 7/28/93,<br>Docket# OPPTS-<br>44600   |
| 1,1,1-Trichloro-ethane | 71-55-6  | HERTOXTERA<br>Developmental study        | Non-TSCA<br>Protocol/Guideline<br>(see docket #<br>OPTS-42059B) | rabbits | inhalation, days 6-15<br>of gestation      | 0, 1000, 3000,<br>6000 ppm | unreported<br>number of<br>females       | There was a decrease in maternal weight gain and food consumption (3000 and 6000 ppm). Clinical observations included ocular discharge, loose feces, and decreased body weight gain (6000 ppm). Percentage of live fetuses per litter was reduced at 6000 ppm. The no-observed effect level (NOEL) was 1000 ppm.   | 52 FR 26564; 7/15/87<br>Fiche# OTS0510654          |
| 1,1,1-Trichloro-ethane | 71-55-6  | HERTOXTERA<br>Developmental study        | Non-TSCA<br>Protocol/Guideline<br>(see docket #<br>OPTS-42059B) | rats    | inhalation, days 6-15<br>of gestation      | 0, 1000, 3000,<br>6000 ppm | unreported<br>number of<br>females       | Observations included decreases in maternal weight gain and food consumption (3000 and 6000 ppm). Maternal clinical observations were hypoactivity at 3000 and 6000 ppm, perioral wetness, and encrustation (6000 ppm). At 6000 ppm non-viable implantations/litters were increased compared to controls. The no-observable effect level (NOEL) was 1000 ppm.  | 52 FR 26564; 7/15/87<br>Fiche# OTS0510654          |
| N-Methyl-pyrrolidone   | 872-50-4 | HEADME<br>Pharmacokinetics               | 40 CFR 795.232<br>(modified)                                    | rat     | inhalation                                 | 10 and 100 ppm             | 4/sex                                    | No NMP was detected in plasma after exposure to 10 ppm. The half-life of NMP could not be determined. Approximately 7% of 10 ppm [2- <sup>14</sup> C] NMP vapor was absorbed and 9% of 100 ppm [2- <sup>14</sup> C] NMP was absorbed. Once absorbed NMP was distributed, metabolized, and eliminated in the urine with negligible tissue residues remaining after 4-5 days post dose.  | 61 FR<br>3403; 1/31/96,<br>Docket# OPPTS-<br>44620 |
| N-Methyl-pyrrolidone   | 872-50-4 | HEADME<br>Pharmacokinetics               | 40 CFR 795.232<br>(modified)                                    | rat     | dermal                                     | 10 mg/kg                   | 5/sex                                    | No NMP was detected in plasma after exposure to 10 mg/kg. The half-life of NMP could not be determined after dermal exposure. Approximately 44% and 43% of the topically applied dose was absorbed by male and female rats, respectively. NMP was readily absorbed after dermal exposure. Once absorbed NMP was distributed, metabolized, and eliminated in the urine with negligible tissue residues remaining after 4-5 days post dose.  | 61 FR<br>3403; 1/31/96,<br>Docket# OPPTS-<br>44620 |
| N-Methyl-pyrrolidone   | 872-50-4 | HEADME<br>Pharmacokinetics               | 40 CFR 795.232<br>(modified)                                    | rat     | oral, 7 days                               | 5, 50 mg/kg                | 10/sex (5<br>mg/kg), 4/sex<br>(50 mg/kg) | No NMP was detected in plasma after exposure to 5 mg/kg. The time to reach $C_{max}$ ( $T_{max}$ ) was 2 hours after the multiple oral high dose. The half-life of NMP could not be determined after low oral exposure. The oral bioavailability of NMP was 48% for male rats and 101% for female rats. NMP was readily absorbed after inhalation exposure. Once absorbed NMP was distributed, metabolized, and eliminated in the urine with negligible tissue residues remaining after 4-5 days post dose.  | 61 FR<br>3403; 1/31/96,<br>Docket# OPPTS-<br>44620 |

## Results of Testing

| Chemical Name                | CAS No.  | Study Code/Type                                     | Protocol/Guideline         | Species | Exposure             | Dose/Concentration         | No. per Group                                  | Results   | Reference   |
|------------------------------|----------|---|----------------------------|---------|----------------------|----------------------------|--|---|---|
| <i>N</i> -Methyl-pyrrolidone | 872-50-4 | HEADME Pharmacokinetics                             | 40 CFR 795.232 (modified)  | rat     | intravenous          | 50 mg/kg                   | 9  | The concentration of NMP in plasma ( $C_{max}$ ) was highest after intravenous administration as compared with oral, dermal, or inhalation routes of exposure. The bioavailability of NMP in female rats was probably lower than 101%. The volume of distribution was 0.7 L/kg for male rats and 1.8 L/kg for female rats. Once absorbed NMP was distributed, metabolized, and eliminated in the urine with negligible tissue residues remaining after 4-5 days post dose.  | 61 FR 3403; 1/31/96, Docket# OPPTS-44620                  |
| <i>N</i> -Methyl-pyrrolidone | 872-50-4 | HECTOXCARC Oncogenicity                             | 40 CFR 798.3300 (modified) | mice    | oral (gavage)        |                            |  |   | due 10/99   |
| <i>N</i> -Methyl-pyrrolidone | 872-50-4 | HECTOXCARC Oncogenicity                             | 40 CFR 798.3300 (modified) | rat     | oral (diet)          | 0, 1600, 5000 or 15000 ppm | 62 male; 62 female                             | Based on the observed decrements in body weight and body weight gain in the high-dose males and females, and the increase in the incidence of nephropathy in the high-dose males, a MTD (maximum tolerated dose) appeared to have been achieved. Under the conditions of this study, NMP was not carcinogenic in male and female rats at dietary concentrations up to 15000 ppm.  | 63 FR 35587; 6/30/98, Docket#OPPTS-44649                  |
| <i>N</i> -Methyl-pyrrolidone | 872-50-4 | HENEUR Functional Observational Battery: Subchronic | 40 CFR 798.6050 (modified) | rat     | oral (diet), 90 days | 3000, 7500, 18,000 ppm     | 20/sex (3000 and 7500 ppm), 26/sex (18000 ppm) | A statistically increase in foot splay was observed in high- and mid-dose males, no such change occurred in females. A statistically significant increase in the incidence of "low" arousal was observed in low-dose males at week 4, but not after that. Similarly, a statistically significant increase in slight palpebral closure was observed in low- and high-dose animals, but only on weeks 4 and 13. It was concluded that the test substance was not neurotoxic.  | 61 FR 3403; 1/31/96 Fiche# OTS0513411-7, Docket No. 44620 |
| <i>N</i> -Methyl-pyrrolidone | 872-50-4 | HENEUR Motor Activity: Subchronic                   | 40 CFR 798.6200 (modified) | rat     | oral (diet), 90 days | 3000, 7500, 18,000 ppm     | 20/sex (3000 and 7500 ppm), 26/sex (18000 ppm) | A statistically increase in foot splay was observed in high- and mid-dose males, no such change occurred in females. A statistically significant increase in the incidence of "low" arousal was observed in low-dose males at week 4, but not after that. Similarly, a statistically significant increase in slight palpebral closure was observed in low- and high-dose animals, but only on weeks 4 and 13. There were no statistically significant effects on motor activity in any dose group of either sex. It was concluded that the test substance was not neurotoxic.   | 61 FR 3403; 1/31/96 Fiche# OTS0513411-7, Docket No. 44620 |
| <i>N</i> -Methyl-pyrrolidone | 872-50-4 | HENEUR Neuropathology: Subchronic                   | 40 CFR 798.6400 (modified) | rat     | oral (diet), 90 days | 3000, 7500, 18,000 ppm     | 20/sex (3000 and 7500 ppm), 26/sex (18000 ppm) | Administration of 7500 and 18000 ppm caused decrements in body weight and body weight gain which were correlated with lower food consumption and food efficiency. There were no compound-related adverse effects on survival, clinical signs of toxicity, ophthalmoscopically visible structures of the eyes, or clinical pathology parameters. No compound-related changes were detected in nervous system tissue or muscle tissue in any treated animal. There were no compound-related adverse effects on organ weight parameters or tissue morphology in any treated animals. The NOEL was 3000 ppm for this study. | 61 FR 3403; 1/31/96 Fiche# OTS0513411-7, Docket No. 44620 |

## Results of Testing

| Chemical Name        | CAS No.  | Study Code/Type                      | Protocol/Guideline         | Species                 | Exposure                                       | Dose/Concentration                          | No. per Group                                   | Results  | Reference   |
|----------------------|----------|--------------------------------------|----------------------------|-------------------------|--|---|---|--|---|
| N-Methyl-pyrrolidone | 872-50-4 | STOX<br>Repeated dose toxicity study | OECD 407                   | B6C3F <sub>1</sub> mice | oral (diet), 4 wk                              | 0, 500, 2500, 7500, 10,000 ppm (nominal)    | 5/sex/group                                     | At 10,000 ppm, one male died during the study, and cloudy swelling of the epithelia of the distal parts of the renal tubules was observed in 4 males and 3 females. At 7500 ppm, no animals died. Cloudy swelling of the epithelia of the distal parts of the renal tubules occurred in 2 males at 7500 ppm. The No Observed Adverse Effect Level (NOAEL) was 2500 ppm.  | 59 FR33291; 6/28/94<br>Fiche# OTS0513411-7, Docket# OPPTS-44610 |
| N-Methyl-pyrrolidone | 872-50-4 | STOX<br>Subchronic oral toxicity     | 40 CFR 798.2650 (modified) | rat                     | oral (diet), 28 days                           | 0, 2000, 6000, 18,000, 30,000 ppm (nominal) | 5/sex/group                                     | Decreased food consumption and efficiency resulted in significant body weight decrements in males and females at the 30,000 ppm level, and in male rats at 18,000 ppm. Alterations in clinical chemical parameters indicate possible compound related changes in lipid, protein, and carbohydrate metabolism at 30,000 ppm. The hematologic and organ weight changes observed were due to reduced body weight, except for centrilobular hepatocellular hypertrophy found at 30,000 and 18,000 ppm levels. The No Observed Adverse Effect Level (NOAEL) was 6000 ppm.   | 59 FR33291; 6/28/94<br>Fiche# OTS0513411-7, Docket# OPPTS-44610 |
| N-Methyl-pyrrolidone | 872-50-4 | STOX<br>Subchronic oral toxicity     | 40 CFR 798.2650 (modified) | B6C3F <sub>1</sub> mice | diet, 3 months (main group), 4 wks (satellite) | 1000, 2500, 7500 ppm                        | 10/sex  | Substance-related findings in the 2500 and 7500 ppm groups treated for 4 week included dark yellow staining of urine, increase in cholesterol in the females, decrease in triglycerides in the males; a decrease in alkaline phosphatase and calcium was seen in the males in the 7500 ppm group. No substance-related effects were noted in the 1000 ppm satellite dose groups. Substance-related findings in the main group included dark yellow staining of urine, significantly increased mean absolute and relative liver weights in male mice at 2500 and 7500 ppm. Centrilobular hypertrophy of the liver cells occurred in the 7500 ppm dose group. No substance-related effects were found in the main group at 1000 ppm. The NOEL was 1000 ppm for this study. | 61 FR 3403; 1/31/96, Docket# OPPTS-44620                        |
| N-Methyl-pyrrolidone | 872-50-4 | STOX<br>Subchronic oral toxicity     | 40 CFR 798.2650 (modified) | rat                     | oral (diet), 90 days                           | 3000, 7500, 18,000 ppm                      | 20/sex (3000 and 7500 ppm), 26/sex (18,000 ppm) | There were no compound-related effects on organ weight parameters or tissue morphology in males or females at any dietary concentration. No compound-related changes were detected in the nervous system tissue or muscle tissue at any concentration in either males or females. The NOEL was considered to be 3000 ppm for both sexes based on compound-related adverse effects on body weight, body weight gain, food consumption, food efficiency, and changes in 3 neurobehavioral parameters (male rats only) at 7500 and 18000 ppm.   | 61 FR 3403; 1/31/96, Docket# OPPTS-44610                        |

## Results of Testing

| Chemical Name             | CAS No.  | Study Code/Type                       | Protocol/Guideline                                      | Species                 | Exposure            | Dose/Concentration                                     | No. per Group     | Results  | Reference                                 |
|---------------------------|----------|---------------------------------------|---|-------------------------|---------------------|--|-------------------|--|---|
| 1,3,5-trimethylbenzene    | 108-67-8 | HESTOX<br>Subacute toxicity           | 40 CFR 798.2650 (modified)                              | rat                     | gavage, 90 days     | 50, 200, 600 mg/kg                                     | 10/sex            | No test substance-related deaths occurred during the study. Clinical signs observed predominantly in the high dose animals consisted of discolored inguinal fur, wet inguinal fur, and salivation. Cumulative body weight gain was decreased approximately 11% in high dose males. No treatment-related ophthalmic lesions were observed following the 90 day treatment. Treatment-related changes in clinical chemistry parameters consisted of increases in phosphorus levels and liver and kidney weight in the 600 mg/kg dose group. The NOEL was 200 mg/kg in this study. | 60 FR 32320; 6/21/95, Docket# OPPTS-44618 |
| 1,3,5-trimethylbenzene    | 108-67-8 | HESTOX<br>Subchronic toxicity         | 40 CFR 798.2650 (modified)                              | rat                     | gavage, 14 days     | 60, 150, 600 mg/kg                                     | 10/sex            | No mortality was observed during the study. No adverse clinical signs were observed; however, wet inguinal fur was observed in high dose males. No treatment-related effects were noted on body weight, body weight gain, or food consumption. No treatment-related ophthalmic lesions were observed following treatment. No treatment-related lesions were observed at necropsy. Treatment-related changes in clinical pathology included increases in cholesterol levels and liver weight in the 150 and 600 mg/kg dose groups. The NOEL was 60 mg/kg for this study.        | 60 FR 19590; 4/19/95, Docket# OPPTS-44616 |
| 1,1,2,2-tetrachloroethane | 79-34-5  | HESTOX<br>Subchronic toxicity         | Non-TSCA Protocol/ Guideline (see docket# OPPTS-42111C) | rat                     | gavage, 14 days     | 0, 50, 100, 200 mg/kg                                  | 10/sex/dose       | Under the conditions of the study, 1,1,2,2-tetrachloroethane exhibited very little ability to cause damage of any organ system monitored. CNS depression was the more prominent effect, occurring in responses to the lowest dose administered, 50 mg/kg. CNS depression limited the oral dose which could be given to rats. The highest dose given, 200 mg/kg, loss of body weight and death of some animals occurred. CNS effects did not persist with full recovery occurring upon termination of exposure.   | 4/18/96, Docket# OPPTS-42111C             |
| Cumene                    | 98-82-8  | EEATOX<br>Mysid shrimp acute toxicity | 40 CFR 797.1930 (modified)                              | <i>Mysidopsis bahia</i> | flow-through, 96 hr | 0, 0.40, 0.60, 1.0, 1.7, 3.3, 4.3 mg/L (mean measured) | 20 (10/replicate) | The 96-hour LC <sub>50</sub> (and 95% confidence limits) was 1.2 (1.0-1.4) mg/L, indicative of moderate toxicity. The NOEC was 0.40 mg/L.  | 55 FR 11253 3/27/90<br>Fiche# OTS0532653  |
| Cumene                    | 98-82-8  | EEATOX<br>Fish acute toxicity         | 40 CFR 797.1400 (modified)                              | rainbow trout           | flow-through, 96 hr | 0, 0.87, 1.2, 1.9, 2.8, 4.9, 6.4 mg/L (mean measured)  | 20 (10/replicate) | The 96-hour LC <sub>50</sub> (and 95% confidence limits) was 4.8 (4.2-5.5) mg/L, indicative of moderate toxicity. The NOEC was 1.9 mg/L.   | 55 FR 11253 3/27/90<br>Fiche# OTS0532653  |
| Cumene                    | 98-82-8  | EEATOX<br>Mysid shrimp acute toxicity | 40 CFR 797.1930 (modified)                              | <i>Mysidopsis bahia</i> | flow-through, 96 hr | 0, 0.22, 0.38, 0.68, 1.1, 2.0 mg/L (mean measured)     | 20 (10/replicate) | The 96-hour LC <sub>50</sub> (and 95% confidence limits) was 1.3 (1.1-2.0) mg/L, indicative of moderate toxicity. The NOEC was 0.68 mg/L.  | 55 FR 11253 3/27/90<br>Fiche# OTS0532653  |
| Cumene                    | 98-82-8  | EEATOX<br>Fish acute toxicity         | 40 CFR 797.1400 (modified)                              | sheepshead minnow       | flow-through, 96 hr | 0, 2.9, 4.3, 5.6, 8.1, 14, 17 mg/L                     | 20 (10/replicate) | The 96-hour LC <sub>50</sub> (and 95% confidence limits) was 5.7 (4.3-8.1) mg/L, indicative of moderate toxicity. The NOEC was <2.9 mg/L.  | 55 FR 11253 3/27/90<br>Fiche# OTS0532653  |
| Cumene                    | 98-82-8  | EEATOX<br>Acute invertebrate toxicity | 40 CFR 797.1300 (modified)                              | <i>Daphnia magna</i>    | flow-through, 48 hr | 0, 1.5, 2.4, 6.1, 8.9 mg/L (mean measured)             | 20 (10/replicate) | The 48-hour EC <sub>50</sub> (and 95% confidence limits) was 3.5 (3.1-4.0) mg/L for filtered samples and 4.0 (3.5-4.5) mg/L for unfiltered samples. The NOEC was 2.4 mg/L.   | 55 FR 11253 3/27/90<br>Fiche# OTS0532653  |

## Results of Testing

| Chemical Name | CAS No. | Study Code/Type   | Protocol/Guideline   | Species   | Exposure  | Dose/Concentration  | No. per Group  | Results  | Reference                                 |
|---------------|---------|---|--|---|---|---|----------------|--|---|
| Cumene        | 98-82-8 | EEBDEG<br>Aerobic Aquatic<br>Biodegradation   | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-<br>42074A) | freshwater<br>sediment and<br>aquatic micro-<br>organisms | glass/teflon ecocores<br>incubated at 23 °C in<br>darkness; 10 days | 2.5 mg/L <sup>14</sup> C-cumene                                 | Not applicable | Cumene was not detectable after 10 days. First-order<br>cumene mineralization and disappearance rate constants of<br>0.02/day and 0.28/day, respectively, were calculated from the<br>data.  | 55 FR 357; 1/4/90<br>Fiche# OTS0522882    |
| Cumene        | 98-82-8 | EFTSPTVOLZ<br>Volatilization study  | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-<br>42074A) | Not applicable  | water   | Not specified   | Not applicable | The ratio of volatilization rate to oxygen re-aeration rate<br>( $k_v/k_a$ ) was 0.49±0.09 at 23 °C.   | 54 FR 39806; 9/28/89<br>Fiche# OTS0522879 |
| Cumene        | 98-82-8 | HEADME<br>Pharmacokinetic study   | 40 CFR 795.230   | rats  | intravenous, single<br>dose   | 33 mg/kg  | 4/sex/group    | Males excreted 61% in urine and females excreted 67% of<br>radiolabel in urine within 24 hours post-dosing, and 79 and<br>77%, respectively, within 72 hours. Fecal excretion was<br>minimal ( $\leq 1.1\%$ ) in 72 hours. Exhaled breath contained a<br>total of 8.4% (males) and 8.6% (females) as volatile<br>compounds, and less than 0.1% of radiolabel. Carcasses<br>retained 0.34% (males) and 0.22% (females) of radiolabel.<br>Terminal half-life in blood for radiolabel was 8.6 hours<br>(males) and 7.3 hours (females). 2-Phenyl-1,2-propanediol<br>and 2-phenylpropionic acid, plus 6 unknown metabolites<br>were isolated in urine. | 55 FR 357; 1/4/90<br>Fiche# OTS0522880    |
| Cumene        | 98-82-8 | HEADME<br>Pharmacokinetic study   | 40 CFR 795.230   | rats  | inhalation (nose only),<br>48 or 72 hr                              | 102, 525, 1328 ppm<br>(mean measured)                           | 4/sex/group    | Excretion of the absorbed dose was rapid; >95% of<br>radiolabel was excreted within 72 hours of the beginning of<br>exposure to all 3 exposure levels. Urine was the major<br>route. Fecal elimination accounted for 2-5% of radiolabel,<br>and exhalation accounted for 8-17%. Distribution was wide,<br>and accumulation was mainly in adipose tissue, liver, kidney,<br>and skeletal muscles. Terminal half-life estimates for<br>cumene, itself, are 17-30 hours.  | 55 FR 357; 1/4/90<br>Fiche# OTS0522880    |
| Cumene        | 98-82-8 | HEADME<br>Pharmacokinetic study   | 40 CFR 795.230   | rats  | oral (gavage), single<br>dose or repeat dose, 8<br>days             | 33 or 1350 mg/kg<br>(single dose); 33 mg/kg<br>(repeat dose)    | 4/sex/dose     | Single exposure rats excreted $\geq 90\%$ of radiolabel within 72<br>hours. Low-dose rats excreted about 88% of radiolabel in<br>urine, and high-dose rats, 72%. In 72 hours, $\leq 3.3\%$ of<br>radiolabel was eliminated in feces, while in exhaled air,<br>values were $\leq 4.9\%$ in low-dose animals and 12-15% in high-<br>dose rats. Repeat-exposure rats followed a pattern similar to<br>that of single low-dose rats. Distribution was primarily to<br>liver, kidney, and adipose tissue in all treatment groups. 2-<br>Phenyl-1,2-propanediol and 2-phenylpropionic acid, plus 6<br>unknown metabolites were isolated in urine.        | 55 FR 357; 1/4/90<br>Fiche# OTS0522880    |
| Cumene        | 98-82-8 | HECTOXTRFM<br>Morphological<br>transformation of<br>BALB/3T cells<br>(Voluntary test) | Non-TSCA<br>Protocol/Guideline                                   | mice,<br>BALB/3T3<br>cells                                | <i>in vitro</i>   | 0, 50, 100, 150, 200,<br>250, 300, 400, 500<br>$\mu\text{g/mL}$ | Not applicable | High toxicity prevented analysis of transformation in cell<br>cultures exposed to concentrations ranging from 250 to 500<br>$\mu\text{g/mL}$ . Cell survival was concentration-related and ranged<br>from 4 to 102% at concentrations of 200-50 $\mu\text{g/mL}$ . The<br>treatment did not increase the numbers of Type III foci,<br>indicating that the compound was negative for cell<br>transformation in the mouse under the conditions of the<br>studies.  | 52 FR 27452; 7/21/87<br>Fiche# OTS0522854 |

## Results of Testing

| Chemical Name | CAS No. | Study Code/Type   | Protocol/Guideline             | Species                                     | Exposure                                   | Dose/Concentration                         | No. per Group        | Results  | Reference                                 |
|---------------|---------|---|--------------------------------|---|--|--|----------------------|--|---|
| Cumene        | 98-82-8 | HEGTOXCHRM<br>Mammalian<br>cytogenetics assay<br>(Voluntary test)                   | Non-TSCA<br>Protocol/Guideline | Chinese ham-<br>sters, ovary<br>cells (CHO) | <i>in vitro</i>                            | 19 to 225 µg/mL                            | Not applicable       | No treatment-related increases were noted in chromosomal aberrations in the presence or absence of metabolic activation at concentrations encompassing the level of cytotoxicity.  | 52 FR 27452; 7/21/87<br>Fiche# OTS0522852 |
| Cumene        | 98-82-8 | HEGTOXDNAF<br>Unscheduled DNA<br>synthesis<br>(Voluntary test)                      | Non-TSCA<br>Protocol/Guideline | rats, primary<br>hepatocytes                | <i>in vitro</i>                            | 1 to 128 µg/mL                             | Not applicable       | No evidence of treatment-related effects on DNA synthesis were noted.  | 52 FR 27452; 7/21/87<br>Fiche# OTS0522853 |
| Cumene        | 98-82-8 | HEGTOXMUTA<br>Mutagenicity study<br>(Ames study)<br>(Voluntary test)                | Non-TSCA<br>Protocol/Guideline | <i>Salmonella typhimurium</i>               | <i>in vitro</i>                            | 0.01, 0.04,<br>0.2 mg/plate                | Not applicable       | The test material was not mutagenic to the test strains (TA98, TA100, TA1535, and TA1537) with or without metabolic activation. At 0.2 mg/plate, the test material was toxic to all four test strains.   | 52 FR 27452; 7/21/87<br>Fiche# OTS0512312 |
| Cumene        | 98-82-8 | HEGTOXMUTA<br>Gene mutations in<br>somatic cells<br>(CHO/HGPRT)<br>(Voluntary test) | Non-TSCA<br>Protocol/Guideline | hamsters                                    | <i>in vitro</i>                            | 100 to 225 µg/mL                           | Not specified        | No evidence of treatment-related increased incidence of forward mutations was observed in the presence or absence of exogenous activation at levels encompassing cytotoxicity.   | 52 FR 27452; 7/21/87<br>Fiche# OTS0522853 |
| Cumene        | 98-82-8 | HENEUR<br>Functional<br>Observational Battery                                       | 40 CFR 798.6050<br>(modified)  | rats  | inhalation, 6 hr/d, 5<br>d/wk, 13 wks      | 0, 100, 496, 1202 ppm<br>(mean measured)   | 21/sex/group         | No treatment-related effects were seen.  | 55 FR 357; 1/4/90<br>Fiche# OTS0522881    |
| Cumene        | 98-82-8 | HENEUR<br>Neuropathology  | 40 CFR 798.6400<br>(modified)  | rats  | inhalation, 6 hr/d, 5<br>d/wk, 13 wks      | 0, 100, 496, 1202 ppm<br>(mean measured)   | 21/sex/group         | Ataxia was seen in high-dose rats during the first 17 days of treatment. Exposure-related ocular effects were seen (swelling and cataracts). Histopathological examination did not reveal exposure-related changes in tissues of peripheral or central nervous systems.  | 55 FR 357; 1/4/90<br>Fiche# OTS0522881    |
| Cumene        | 98-82-8 | HENEUR<br>Motor activity test   | 40 CFR 798.6200<br>(modified)  | rats  | inhalation, 6 hr/d, 5<br>d/wk, 13 wks      | 0, 100, 496, 1202 ppm<br>(mean measured)   | 21/sex/group         | Decreased motor activity was noted in the 2 highest exposure groups at weeks 4, 9, and 13. Gait abnormalities, decreased rectal temperature, and increased activity were noted at 1 hour after the first exposure.   | 55 FR 357; 1/4/90<br>Fiche# OTS0522881    |
| Cumene        | 98-82-8 | HERTOXTERA<br>Developmental<br>toxicity study                                       | 40 CFR 798.4350                | rabbits                                     | inhalation, 6 hr/d;<br>gestation days 6-18 | 0, 492, 1206, 2297 ppm<br>(mean measured)  | 15/exposure<br>level | Maternal toxicity was noted at 500 ppm (dose-related decreased body weight gain). No evidence of treatment-related embryotoxicity, fetotoxicity or teratogenicity were noted.  | 55 FR 357; 1/4/90<br>Fiche# OTS0522881    |
| Cumene        | 98-82-8 | HERTOXTERA<br>Developmental<br>toxicity study                                       | 40 CFR 798.4350                | rats  | inhalation, 6 hr/d;<br>gestation days 6-15 | 0, 100, 500, 1200 ppm<br>(mean analytical) | 25/group             | Maternal toxicity was noted at 500 and 1200 ppm, evidenced at 1200 ppm by significant reductions in body weight gain and treatment-related clinical signs of toxicity (perioral wetness and perioral encrustations) following daily exposures as well as during exposures (hypoactivity and blepharospasm), decreased food consumption during the exposure period and increased relative liver weight at necropsy. Reduced food consumption and clinical observations during exposure were observed at 500 ppm as well. Gestational parameters (viable implantations per litter, sex ratio, fetal body weights) were unaffected by exposure. | 55 FR 357; 1/4/90<br>Fiche# OTS0522881    |



## Results of Testing

| Chemical Name           | CAS No.    | Study Code/Type                          | Protocol/Guideline         | Species  | Exposure   | Dose/Concentration   | No. per Group           | Results   | Reference                               |
|-------------------------|------------|--|----------------------------|--|--|--|-------------------------|---|---|
| Cumene                  | 98-82-8    | HESTOX<br>Subchronic inhalation toxicity | 40 CFR 798.2450 (modified) | rats   | inhalation, 6 hr/d, 5 d/wk, 13 wks   | 0, 100, 496, 1202 ppm (mean measured)  | 21/sex/group            | No exposure-related mortalities occurred. Minimal hematologic changes (increased leukocytes, lymphocytes, and platelets) and serum chemistry changes (increased total protein, albumin, globulin, calcium, and phosphorus; decreased glucose) were noted at 496 ppm and higher. Exposure-related increased mean absolute and relative weights of liver, kidneys, and adrenal glands were noted. Histopathological examination revealed kidney lesions in these groups.  | 55 FR 357; 1/4/90<br>Fiche# OTS0522881  |
| 4-Nonylphenol, Branched | 84852-15-3 | EEATOX<br>Acute algal toxicity           | 40 CFR 797.1050            | <i>Skeletonema costatum</i> (marine alga)          | static, 96 hr  | 0, 0.015, 0.03, 0.06, 0.12, 0.24 mg/L (nominal)  | Not specified           | Exposure to the algae to the test substance for 96-hours resulted in a median effective concentration (EC <sub>50</sub> ) of 0.024 mg/L. Algae transferred from the flasks containing the highest concentration that allowed any algal survival (0.12 mg/L) to a flask containing fresh media without the test substance grew from 15,950 to 1,220,000 cells per mL during the 48-hrs following the conclusion of the test, indicating a lack of algistatic effect.   | 55 FR 53348; 12/28/90 Fiche# OTS0531523 |
| 4-Nonylphenol, Branched | 84852-15-3 | EEATOX<br>Acute mysid shrimp toxicity    | 40 CFR 797.1930            | <i>Mysidopsis bahia</i> (mysid shrimp)             | flow through, 96 hr  | 0, 0.006, 0.010, 0.016, 0.025, 0.042 mg/L (nominal)  | 20/group (10/replicate) | Exposure of mysids to the test substance resulted in a 96-hour median lethal concentration (LC <sub>50</sub> ) of 0.042 mg/L. The mean percent of mysids surviving was: 100% in control, 0.006, 0.010, and 0.016 mg/L; 85% at 0.025 mg/L; and 40% at 0.042 mg/L. A portion of the mysids exposed to 0.042 mg/L were pale from 24-hours until the end of the test. No other sublethal effects were observed during the test. The no observed effect concentration (NOEC) is 0.016 mg/L.  | 55 FR 53348; 12/28/90 Fiche# OTS0531523 |
| 4-Nonylphenol, Branched | 84852-15-3 | EEATOX<br>Chironomid sediment toxicity   | 40 CFR 795.4050            | <i>Chironomus tentans</i> (midge)                  | flow through, 20 °C, 14 days. 3 exposures: aqueous with minimal sand substrate (dosed water); aqueous in presence of sediment (interstitial water); sediment in presence of untreated water column (dosed sediment). | 0.023, 0.044, 0.076, 0.150, 0.320 mg/L (dosed water); 0.00719, 0.0205, 0.0387, 0.081, 0.146 mg/L (interstitial water); 2.34, 4.79, 9.51, 20.1, 34.2 mg/kg (dosed sediment) | 10                      | LC <sub>50</sub> = 0.119 mg/L (dosed water), 0.075 mg/L (interstitial water). There was insufficient mortality to calculate a LC <sub>50</sub> for dosed sediment. MACT for survival were 0.107 mg/L (dosed water), 0.056 mg/L (interstitial water), and 26 mg/kg (dosed sediment). EC <sub>50</sub> based on observed adverse effects (paleness, reduced size, lethargy, and mortality) were 0.095 mg/L (dosed water) and 0.041 mg/L (interstitial water). There were insufficient adverse effects to calculate a E <sub>50</sub> for sediment. MACT for growth were 0.107 mg/L (dosed water), 0.030 mg/L (interstitial water), and 26 mg/kg (dosed sediment). | Docket# OPPTS-42104B                    |
| 4-Nonylphenol, Branched | 84852-15-3 | EEATOX<br>Acute algal toxicity           | 40 CFR 797.1050            | <i>Selenastrum capricornutum</i> (freshwater alga) | static, 96 hr  | 0, 0.06, 0.12, 0.25, 0.50, 1.0 mg/L (nominal)  | 3 replicates/group      | Exposure of algae to the test substance for 96-hours resulted in a median effective concentration (EC <sub>50</sub> ) of 0.50 mg/L. Algae transferred from the test flasks containing the highest tested concentration to a flask containing fresh media without the test substance grew from 9700 to 1,940,000 cells per mL during the 7 days following the conclusion of the test, indicating a lack of algistatic effect.  | 55 FR 53348; 12/28/90 Fiche# OTS0531523 |

## Results of Testing

| Chemical Name           | CAS No.    | Study Code/Type                                 | Protocol/Guideline                                    | Species  | Exposure                         | Dose/Concentration                               | No. per Group           | Results   | Reference                                 |
|-------------------------|------------|---|---|--|----------------------------------|--|-------------------------|---|---|
| 4-Nonylphenol, Branched | 84852-15-3 | EEATOX<br>Acute fish toxicity                   | 40 CFR 797.1400 (modified)                            | <i>Cyprinodon variegatus</i> (sheepshead minnow) | flow through, 96 hr              | 0, 0.075, 0.125, 0.19, 0.31, 0.50 mg/L (nominal) | 20/group (10/replicate) | Exposure of fish to the test substance resulted in a 96-hour median lethal concentration (LC <sub>50</sub> ) of 0.31 mg/L. The mean percent of fish surviving was: 95-100% in control, 0.75, 0.125, 0.19, and 0.31 and 0% at 0.50 mg/L. All fish exposed to 0.50 mg/L were lethargic, bloated, and/or exhibiting a loss of equilibrium from 24 hours until they died. No other sublethal effects were observed during the test. The no observed effect concentration (NOEC) is 0.31 mg/L.   | 55 FR 53348; 12/28/90 Fiche# OTS0531523   |
| 4-Nonylphenol, Branched | 84852-15-3 | EEBIOC<br>Fish bioconcentration                 | 40 CFR 797.1520                                       | fathead minnow                                   | flow-through, unaerated, 20 days | 4.9, 22.7 µg/L                                   | Not specified           | After the test exposure period, the animals were exposed to diluted water without the test substance for 7 days. The BCF was 344, with an uptake rate constant of 193, and a depuration rate constant of 0.56 at 22.7 µg/L. The BCF was 271, with an uptake rate constant of 133, and a depuration rate constant of 0.49 at 4.9 µg/L.   | 57 FR 3203; 1/28/92, Docket# OPPTS-44580  |
| 4-Nonylphenol, Branched | 84852-15-3 | EECLIF<br>Fish early life stage                 | 40 CFR 797.1600                                       | <i>Pimephales promelas</i> (fathead minnow)      | flow-through, 33 days            | 0, 3.0, 6.0, 9.0, 15, 25 µg/L (nominal)          | 60/group (30/replicate) | Exposure of embryos, larvae, and juvenile fish to the test material resulted in a lowest observed effect level (LOEL) of 14 µg/L, a no observed effect level (NOEL) of 9.0 µg/L, and a maximum acceptable toxicant concentration (MATC) of 10.2 µg/L. The most sensitive measured effect was survival of fathead minnows at the conclusion of the test. Fish exposed to the control and the 3.0, 6.0, and 9.0 µg/L began to hatch on the 3rd day of exposure, while fish exposed to 14 and 23 µg/L did not begin to hatch until the 4th day. No statistically significant effects were noted at any test concentration of the number of embryos hatched, the time to first feeding, or length and weight of surviving fish. No sublethal effects were noted during the study. | 56 FR 27961; 6/18/91 Fiche# OTS0531525    |
| 4-Nonylphenol, Branched | 84852-15-3 | EECTOX<br>Mysid shrimp chronic toxicity         | 40 CFR 797.1950                                       | <i>Mysidopsis bahia</i> (mysid shrimp)           | flow-through, 28 days            | 0, 4, 8, 12, 18, 30 µg/L                         | Not specified           | Exposure to mysids to the test material resulted in a lowest observed effect level (LOEL) of 8 µg/L, a no observed effect level (NOEL) of 4 µg/L, and a maximum acceptable toxicant concentration (MATC) of 5.1 µg/L. The total length of surviving mysids was the most sensitive biological parameter measured. Other parameters were survival of mysids after 28 days, the number of young per female, and sublethal effects.   | 56 FR 27961; 6/18/91 Fiche# OTS0531525    |
| 4-Nonylphenol, Branched | 84852-15-3 | EECTOX<br>Tadpoles/sediment subchronic toxicity | Non-TSCA Protocol/Guideline (see docket #OPTS-42104B) | <i>Rana catesbiana</i>                           | 30 days                          | 36, 57, 155, 390, 680 mg/kg (dry wt)             | 10/replicate            | The LC <sub>50</sub> value is 260 mg/kg. The EC <sub>50</sub> value is 220 mg/kg. The NOEL is 155 mg/kg. The LOEL is 390 mg/kg. The MATC is 250 mg/kg.  | 57 FR 21657; 5/21/92, Docket# OPPTS-44585 |
| 4-Nonylphenol, Branched | 84852-15-3 | EFBDEG<br>Microcosm biodegradation (ecocore)    | Non-TSCA Protocol/Guideline (see docket #OPTS-42104B) | Not applicable                                   | 25 °C, 10 days                   | 5.4 mg/L   | 15 ecocores             | The test substance was determined to not have mineralized. Volatilization played a minor role in removal of the test substance from the ecocores, accounting for an average of less than 1% of the initial spike. The concentration of the test substance in water declined at approximately the same rate over time as in controls. The concentration of the test substance adsorbed to sediment did not decline appreciably and accounted for approximately one-half of the initial spike.  | 56 FR 12202; 3/22/91 Fiche# OTS0531524    |

## Results of Testing

| Chemical Name           | CAS No.       | Study Code/Type                                 | Protocol/Guideline                                    | Species                         | Exposure  | Dose/Concentration               | No. per Group  | Results  | Reference   |
|-------------------------|---------------|---|---|---------------------------------|---|----------------------------------|----------------|--|---|
| 4-Nonylphenol, Branched | 84852-15-3    | EFBDEG<br>Anaerobic aquatic biodegradation      | 40 CFR 796.3140                                       | anaerobic digester sludge       | Not specified   | Not specified                    | Not applicable | The cumulative gas production of the test substance was less than that of the control, resulting in a negative percent of theoretical gas production value. The control substance, ethanol, at a concentration of 50 mg C/L, evolved 101.1% of its theoretical gas production, indicating a viable inoculum and valid test system. | 56 FR 12202; 3/22/91<br>Fiche# OTS0531524   |
| 4-Nonylphenol, Branched | 84852-15-3    | EFPCHE<br>Crystallization point                 | 40 CFR 796.1230 (modified)                            | Not applicable                  | Not applicable  | Not applicable                   | Not applicable | The crystallizing point was determined to be -24.5 °C  | 55 FR 37356; 9/11/90,<br>Fiche# OTS0527282,<br>Docket# OPPTS-44558, 42104               |
| 4-Nonylphenol, Branched | 84852-15-3    | EFPCHE<br>Boiling point                         | 40 CFR 796.1220                                       | Not applicable                  | Not applicable  | Not applicable                   | Not applicable | The boiling point is greater than 573 K. However, data from the present study indicate that the test substance will thermally decompose before boiling.  | 55 FR 37356; 9/11/90,<br>Fiche# OTS052782,<br>Docket# OPPTS-44558, 56 FR 12202; 3/22/91 |
| 4-Nonylphenol, Branched | 84852-15-3    | EFPCHEDISS<br>Dissociation constants            | 40 CFR 796.1370                                       | Not applicable                  | Not specified   | Not specified                    | Not applicable | The mean pK of the test substance was determined to be 10.7, with a range of 10.6 to 10.8.   | 5 55 FR 37356;<br>9/11/90; 56 FR 12202;<br>3/22/91, Fiche# OTS0531524                   |
| 4-Nonylphenol, Branched | 84852-15-3    | EFPCHEPART<br>Partition coefficient             | 40 CFR 796.1550                                       | Not applicable                  | Agitated for 1 hr at 25 °C and centrifuged 10,000 g for 30 min. | 100 µL                           | Not applicable | Mean log K <sub>ow</sub> values at pH 5, 7, and 9 are 4.77, 4.70, and 4.75, respectively.  | 56 FR 12202; 3/22/91,<br>Fiche# OTS0531524  |
| 4-Nonylphenol, Branched | 84852-15-3    | EFPCHEVPRE<br>Vapor pressure                    | 40 CFR 796.1950                                       | Not applicable                  | Not specified   | Not applicable                   | Not applicable | 4.55 x 10 <sup>-3</sup> Pa (std. dev. = 3.54 x 10 <sup>-3</sup> Pa)  | 55 FR 37356; 9/11/90,<br>Fiche# OTS0527282, Docket# OPPTS- 44558, 42104                 |
| 4-Nonylphenol, Branched | 84852-15-3    | EFPCHEWSOL<br>Water solubility                  | 40 CFR 796.1860                                       | Not applicable                  | pH 5, 7, and 9  | Not applicable                   | Not applicable | 4600 µg/L (pH 5), 6237 µg/L (pH 7), 11,897 µg/L (pH 9)   | 55 FR 37356; 9/11/90,<br>Fiche# OTS0527282,<br>Docket# OPPTS-44558, 42104               |
| 4-Nonylphenol, Branched | 84852-15-3    | EFPCHEWSOL<br>Water solubility                  | 40 CFR 796.1860                                       | Not applicable                  | seawater  | Not applicable                   | Not applicable | The seawater solubility value was calculated as the mean dissolved test substance concentration in the three test samples. The solubility of the test substance in artificial seawater was determined to be 3.63 mg/L.   | 56 FR 12202; 3/22/91<br>Fiche# OTS0531524   |
| 4-Nonylphenol, Branched | 84852-15-3    | EFTSPT<br>Soil and sediment adsorption isotherm | 40 CFR 796.2750                                       | Not applicable                  | 6 days (equilibrium achieved on day 3)                          | 10, 20, 40, 60, 80, and 100 mg/L | Not applicable | The results of this study indicate that the test substance may be expected to adsorb strongly to soils and sediments in the environment.   | 56 FR 12202; 3/22/91,<br>OTS,0531524  |
| Cereclor S52®           | Not available | EECTOX<br>Mollusk chronic toxicity              | Non-TSCA Protocol/Guideline (see docket # OPTS-42004) | <i>Mytilus edulis</i> (mussels) | flow-through, 60 days   | 0.22, 3.9 mg/L (measured)        | 50             | There were no mortalities of the test animals exposed to the test material (Cereclor S52). A slight decrease in food consumption (filtration) at the higher concentration level was noted.   | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0507258   |
| Cereclor S52®           | Not available | EECTOX<br>Chronic fish toxicity                 | Non-TSCA Protocol/Guideline (see docket # OPTS-42004) | Rainbow trout                   | flow-through, 60 days   | 1.0, 1.05, 4.5 mg/L (measured)   | 30             | The test material (Cereclor S52) was not toxic to the test animals. There were no sub-lethal or behavioral effects observed.   | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0507258   |

## Results of Testing

| Chemical Name                                   | CAS No.       | Study Code/Type                       | Protocol/Guideline  | Species                            | Exposure                                | Dose/Concentration   | No. per Group                                  | Results   | Reference                                      |
|---|---------------|---------------------------------------|---|------------------------------------|---|--|--|---|--|
| Cereclor S52 <sup>®</sup>                       | Not available | HERTOXTERA<br>Developmental study     | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | rabbits                            | oral (gavage), day 6-27<br>of gestation | 10, 30, 100 mg/kg/d  | 16 pregnant<br>females                         | Exposure to the test material (Cereclor S52) caused no treatment-related effects to mean maternal body weight, number of litters with malformations, or developmental and genetic variations. Treatment with the test material did not induce teratogenic responses at any of the doses tested.   | 48 FR 20132; 5/4/83<br>Fiche# OTS0507252       |
| Cereclor S52 <sup>®</sup>                       | Not available | HERTOXTERA<br>Developmental study     | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | rats                               | oral (gavage), day 6-19<br>of gestation | 500, 2000, 5000<br>mg/kg/d                                       | 25 pregnant<br>females                         | Test animals exposed to the test material (Cereclor S52) at 5000 mg/kg/day exhibited an increased incidence of wet matted and yellow stained haircoat in the anogenital area and soft stool. There were no dose-related differences in mean maternal weight gain, mean uterus weight, and fetal malformations when compared to the controls.  | 49 FR 30114; 7/26/84<br>Fiche# OTS0507334      |
| Cereclor S52 <sup>®</sup>                       | Not available | HESTOX<br>Subchronic study            | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | rats                               | oral (dietary), 13 wks                  | 10, 100, 625 mg/kg/d   | 15 male;<br>15 female                          | Animals exposed to the test material (Cereclor S52) exhibited a slight decrease in body weight gain at 625 mg/kg/day. There were slight increases in serum total protein and cholesterol in females at 625 mg/kg/day. Kidney weights were increased in both sexes at 100 and 625 mg/kg/day. The toxicological no-effect level was 10 mg/kg/day.   | 49 FR 44124; 11/2/84<br>Fiche# OTS0507338      |
| Chlorowax 40 <sup>®</sup>                       | Not available | EECTOX<br>Chronic fish toxicity       | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | Rainbow trout                      | flow-through, 60 days                   | 0.97, 1.0, 4.0 mg/L<br>(measured)                                | 30   | The test material (Chlorowax 40) was not toxic to the test animals. There were no sub-lethal or behavioral effects observed.  | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0507258  |
| Chlorowax 40 <sup>®</sup>                       | Not available | EECTOX<br>Mollusk chronic<br>toxicity | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | <i>Mytilus edulis</i><br>(mussels) | flow-through, 60 days                   | 0.12, 2.18 mg/L<br>(measured)                                    | 50   | There were no mortalities of the test animals exposed to the test material (Chlorowax 40). A slight decrease in food consumption (filtration) at the higher concentration level was noted.  | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0507258  |
| Chlorinated<br>Paraffins: C23, 43% <sup>1</sup> | Not available | HECTOXCARC<br>Carcinogenicity study   | National Toxicology<br>Program (NTP)                        | F344/N rats                        | gavage, 5x/wk for 103<br>weeks          | 0, 875, 3750 mg/kg<br>(male); 0, 100, 300, 900<br>mg/kg (female) | 50 male<br>50 female                           | No evidence of carcinogenicity in male rats at either dose level. Equivocal evidence of carcinogenicity in female rats as shown by an increased incidence of adrenal gland medullary pheochromocytomas.   | NTP TR-305, May<br>1986, NTIS<br>PB86248093/AS |
| Chlorinated<br>Paraffins: C23, 43%              | Not available | HECTOXCARC<br>Carcinogenicity study   | NTP   | B6C3F <sub>1</sub> mice            | gavage, 5x/wk for 103<br>weeks          | 0, 2500, 5000 mg/kg  | 50 male<br>50 female                           | Equivocal evidence of carcinogenicity in male mice as shown by an increased incidence of malignant lymphomas. Equivocal evidence of carcinogenicity in female mice as shown by a marginal increase in the incidence of hepatocellular neoplasms.  | NTP TR-305, May<br>1986, NTIS<br>PB86248093/AS |
| Chlorowax 40 <sup>®</sup>                       | Not available | HERTOXTERA<br>Developmental study     | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | rabbits                            | oral (gavage), day 6-27<br>of gestation | 500, 2000, 5000<br>mg/kg/day                                     | unreported<br>number of<br>pregnant<br>females | Results showed that 3 test animals aborted with the test material (Chlorowax 40), 1 at 2000, and 2 at 5000 mg/kg/day. In the high dose group, there was a slight increase in mean post-implantation loss and a slight decrease in the mean number of viable fetuses when compared to the control. There were no treatment-related effects on mean maternal body weight gain observed at any dose level. | 48 FR 12124; 3/23/83<br>Fiche# OTS0507250      |

<sup>1</sup>Commercial-grade material similar to Clorowax 40C<sup>®</sup> without added stabilizers.

## Results of Testing

| Chemical Name   | CAS No.       | Study Code/Type                        | Protocol/Guideline  | Species  | Exposure  | Dose/Concentration  | No. per Group         | Results   | Reference                                     |
|-----------------|---------------|--|---|--|---|---|-----------------------|---|---|
| Chlorowax 40®   | Not available | HERTOXTERA<br>Developmental study      | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | rat  | oral (gavage in corn oil), gestation day 6 through 19 | 0, 500, 2000, 5000 mg/kg/d  | 25 mated females      | One high-dose female died. No evidence of teratogenicity was noted at any treatment level, nor of embryotoxicity or fetotoxicity.   | 48 FR 20132; 5/4/83<br>Fiche# OTS0507331      |
| Chlorowax 40®   | Not available | HESTOX<br>Subchronic study             | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | rats, mice                                       | oral (gavage), 1x/d; 5 d/wk; 13 wks                   | 235, 469, 938, 1875, 3750 mg/kg (rats)<br>469, 938, 1875, 3750, 7500 mg/kg (mice) | 10 male;<br>10 female | The test material (Chlorowax 40) produced a yellow discoloration of the ingesta in the small intestines of the rats. Scattered white foci were observed in the livers of a small number of female rats. Hepatic lesions were noted in high dose (3750 mg/kg) female rats. In mice, there were no treatment-related or dose-related lesions caused by the test material. The test material appeared to be non-toxic to both rats and mice. | 49 FR 44124; 11/2/84<br>Fiche# OTS0507336     |
| Chlorowax 500C® | Not available | EEATOX<br>Chironomid sediment toxicity | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | <i>Chironomus tentans</i><br>(midges)            | static, 48 hr   | 18-162 µg/L   | 20 (5/replicate)      | No adverse effects were noted up to the limits of solubility.   | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0507261 |
| Chlorowax 500C® | Not available | EEATOX<br>Mysid shrimp acute toxicity  | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | mysid shrimp                                     | flow-through, 96 hr                                   | 14.9 - 84.4 µg/L (mean measured)  | 20 (5/replicate)      | The 96-hour LC <sub>50</sub> was 14.1 µg/L.   | 49 FR 5187; 2/10/84<br>Fiche# OTS0507326      |
| Chlorowax 500C® | Not available | EEATOX<br>Algae acute toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | <i>Skeletonema costatum</i><br>(marine alga)     | static, 10 days                                       | 4.5, 6.7, 12.1, 19.6, 43.1, 69.8 µg/L (measured)                                  | Not applicable        | The test material (Chlorowax 500C) caused a significant decrease in the growth rate of the test species at concentrations of 19.6 µg/L and above. The EC <sub>50</sub> (population growth) value (and 95% confidence limit) was 42.3 µg/L (27.3 to 93.1 µg/L).  | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0507260 |
| Chlorowax 500C® | Not available | EEATOX<br>Algae acute toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | <i>Selenastrum capricornutum</i><br>(green alga) | 10 days   | 0.18, 0.32, 0.56, 1.0, 1.8, 3.2 mg/L (nominal)                                    | Not applicable        | The test material (Chlorowax 500C) had an EC <sub>50</sub> (population growth) value (and 95% confidence interval) of 1.31 mg/L (0.88 to 4.06 mg/L).  | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0507258 |
| Chlorowax 500C® | Not available | EEATOX<br>Daphnid acute toxicity       | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | <i>Daphnia magna</i>                             | static, 48 hr   | 11 to 380 µg/L (mean measured)  | 20 (5/replicate)      | The 48-hour EC <sub>50</sub> (immobilization) was 530 µg/L. The test substance caused the daphnids to float on or near the surface at measured concentrations of 75 µg/L.   | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0507330 |
| Chlorowax 500C® | Not available | EEBIOC<br>Bioconcentration study       | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | mussels  | flow-through, 147 days                                | 2.35, 10.1 µg/L (mean measured)   | 130                   | The test material (Chlorowax 500C) at the higher concentration level killed 33% of the original test animals during the exposure period. At the lower concentration level, 7% of the original test animals died. The BCFs for the whole test animal were 40.9 x 10 <sup>3</sup> (high concentration) and 24.8 x 10 <sup>3</sup> (lower concentration).  | 49 FR 5187; 2/10/84<br>Fiche# OTS0507328      |
| Chlorowax 500C® | Not available | EEBIOC<br>Bioconcentration study       | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | Rainbow trout                                    | flow-through, 168 days                                | 3.1, 14.3 µg/L (mean measured)  | 100                   | The test material (Chlorowax 500C) did not cause any mortalities or adverse effects at any of the concentrations tested. The bioconcentration factors (BCF) ranged from 2800 to 16000 in the liver, 11700 to 15500 in the viscera, and 3600 to 5300 for the whole fish.   | 49 FR 5187; 2/10/84<br>Fiche# OTS0507327      |

## Results of Testing

| Chemical Name   | CAS No.       | Study Code/Type                               | Protocol/Guideline  | Species                               | Exposure                                   | Dose/Concentration   | No. per Group         | Results  | Reference                                     |
|-----------------|---------------|---|---|---------------------------------------|--|--|-----------------------|--|---|
| Chlorowax 500C® | Not available | EECLIF<br>Fish early life stage study         | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | Sheepshead minnow                     | flow-through, 28 days                      | 2.4, 4.1, 6.4, 22.1, 54.8 µg/L (measured)  | 40 (5/replicate)      | The test material (Chlorowax 500C) did not cause any significant effects on hatchability of embryos or on survival of larvae compared to the controls. The no-observed-effect concentration was 54.8 µg/L.   | 49 FR 5187; 2/10/84<br>Fiche# OTS0507320      |
| Chlorowax 500C® | Not available | EECTOX<br>Mollusk chronic toxicity            | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | <i>Mytilus edulis</i><br>(mussels)    | flow-through, 60 days                      | 0.071, 0.13, 0.93 mg/L (measured)  | 50                    | The LC <sub>50</sub> (and 95% confidence level) for the test material (Chlorowax 500C) was 0.074 mg/L (0.068 to 0.081 mg/L).   | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0507258 |
| Chlorowax 500C® | Not available | EECTOX<br>Chironomid chronic toxicity         | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | <i>Chironomus tentans</i><br>(midges) | 49 days                                    | 61-394 µg/L  | 100<br>(25/replicate) | Animals exposed to the test material (Chlorowax 500C) produced no adults at concentration levels of 121 and 394 µg/L. The maximum acceptable toxicant concentration (MATC) for the test material was estimated to be >78 and <121 µg/L.  | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0507261 |
| Chlorowax 500C® | Not available | EECTOX<br>Mysid shrimp chronic toxicity       | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | mysid shrimp                          | flow-through, 28 days                      | 0.6 to 7.3 µg/L (mean measured)  | 20<br>(10/replicate)  | No effects were noted on survival, sexual maturation, reproduction, or final size at any treatment level. The maximum acceptable toxicant concentration (MATC) was >7.3 µg/L.  | 49 FR 5187; 2/10/84<br>Fiche# OTS0507326      |
| Chlorowax 500C® | Not available | EECTOX<br>Chronic fish toxicity               | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | Rainbow trout                         | flow-through, 60 days                      | 0.34, 1.07, 3.05 mg/L (measured)   | 30                    | The test material (Chlorowax 500C) had an LC <sub>50</sub> value (and 95% confidence level) of 0.34 mg/L (0.23 to 0.50 mg/L). At all concentration levels, the test animals displayed abnormal behavior (lethargy and a slow response to the presence of food).  | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0507258 |
| Chlorowax 500C® | Not available | EECTOX<br>Daphnid chronic toxicity            | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | <i>Daphnia magna</i>                  | flow-through, 21 days                      | 3.2, 5.6, 10, 18 µg/L (nominal)  | 20<br>(10/replicate)  | Parent test animals exposed to the test material (Chlorowax 500C) had total mortalities at measured concentrations of 16.3 µg/L and above within 6 days. The 6 to 21 day LC50 value (and 95% confidence limit) was 12.0 µg/L (9.0 to 16.0 µg/L). Offspring exposed to 8.9 µg/L (measured) had a 37% mortality. There were no observed effects on reproduction and growth among the test animals (after 21 days) exposed to 5.6 µg/L. The MATC was between 5.0 and 8.9 µg/L.  | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0507330 |
| Chlorowax 500C® | Not available | EFBDEG<br>Anaerobic biodegradation/inhibition | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | Not applicable                        | Digester, anaerobic sewage sludge, 10 days | 0.56% to 10% w/w (with respect to digester volatile suspended solids (VS) content) | Not applicable        | The toxicity of the test substance to the anaerobic sewage sludge digestion process were assessed by measurement of the degree of inhibition of gas production at various time intervals. The data show that significant (>10%) inhibition of gas production occurred at concentrations of 3.2, 5.6 and 10% (w/w) on VS during the first 3-4 days and continued until day 10 when the experiment was terminated. Concentrations of 0.56, 1.0 and 1.8% (w/w) on VS did not significantly affect digest gas production. It was concluded that concentrations >3.2% (w/w) on VS may cause transient partial inhibition of gas production. However, recovery of affected microorganisms is likely to be rapid with no long-term effects. | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0507328 |

## Results of Testing

| Chemical Name                                   | CAS No.       | Study Code/Type                               | Protocol/Guideline  | Species                 | Exposure  | Dose/Concentration  | No. per Group          | Results  | Reference   |
|---|---------------|---|---|-------------------------|---|---|------------------------|--|---|
| Chlorowax 500C®                                 | Not available | EFBDEG<br>Inherent<br>Biodegradability        | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | Not applicable          | aerobic, 28 days, 22 °C, 200 mg/L<br>activated sludge | 25 and 50 mg of<br>carbon/L   | Not applicable         | Biodegradation was followed by CO <sub>2</sub> evolution by OECD method 203B. No significant biodegradation of chlorinated paraffin occurred under the test conditions. Values of 16.0% and 7.4% of theoretical carbon dioxide evolution were obtained at 25 and 50 mg of carbon/L, respectively. No significant inhibition was noted.   | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0507259,<br>Docket# OPPTS-44003 |
| Chlorinated<br>Paraffins: C12, 60% <sup>2</sup> | Not available | HECTOXCARC<br>Carcinogenicity study           | National Toxicology<br>Program (NTP)                        | F344/N rats             | gavage, 5x/wk for 2 yr                                | 0, 312, 625 mg/kg   | 70 male<br>70 female   | Clear evidence of carcinogenicity based on increased incidence of hepatocellular neoplasms (primarily neoplastic nodules) in male and female rats, of adenomas or adenocarcinomas (combined) of the kidney tubular cells in male rats, and of follicular cell adenomas or carcinomas (combined) of the thyroid gland in female rats. Mononuclear cell leukemia in dosed males was also reported.   | NTP TR-308, May<br>1986, NTIS<br>PB86248101/AS                        |
| Chlorinated<br>Paraffins: C12, 60%              | Not available | HECTOXCARC<br>Carcinogenicity study           | NTP   | B6C3F <sub>1</sub> mice | gavage, 5x/wk for 2 yr                                | 0, 125, 250 mg/kg   | 50 male<br>50 female   | Clear evidence of carcinogenicity based on increased incidence of hepatocellular adenomas and of adenomas or carcinomas (combined) in male and female mice and increased incidences of adenomas or adenomas and carcinomas (combined) of thyroid gland follicular cells in female rats.  | NTP TR-308, May<br>1986, NTIS<br>PB86248101/AS                        |
| Chlorowax 500C®                                 | Not available | HEGTOXTRFM<br>Transformation study            | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | mice                    | <i>in vitro</i>                                       | 31.25, 62.5, 125, 250, 500 µg/mL (non-activation); 6.25, 12.5, 25, 50, 100 µg/mL (activation) | Not specified          | The LC <sub>50</sub> of the test material (Chlorowax 500C) was 44 µg/mL in the absence of metabolic activation and 58 µg/mL in the presence of metabolic activation. In both cases there were increased transformed colonies.  | 47 FR 54160; 12/1/82<br>Fiche# OTS0507248                             |
| Chlorowax 500C®                                 | Not available | HEGTOXCHRM<br>Rodent dominant<br>lethal assay | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | rats                    | oral (gavage) in corn<br>oil, 5 days                  | 0, 250, 750, 2000<br>mg/kg/d  | 15 males               | No evidence of mutagenicity was noted by dominant lethal assay.  | 49 FR 5187; 2/10/84<br>Fiche# OTS0507331                              |
| Chlorowax 500C®                                 | Not available | HERTOXTERA<br>Developmental study             | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | rats                    | oral (gavage), day 6-19<br>of gestation               | 0, 100, 500, 2000<br>mg/kg/d  | 15 pregnant<br>females | There were no treatment-related effects in test animals that received 100 mg/kg/day of the test material (Chlorowax 500C). At 500 and 2000 mg/kg/day, observations included yellow and brown staining of the anogenital haircoat, soft stool, red and brown staining in the nasal region, decreased activity, oily haircoats, emaciation, and excessive salivation. At 2000 mg/kg/day, there was a statistically significant increase in the number of postimplantation losses, and a decrease in the number of viable fetuses. Missing or shortened digits were observed in 19 fetuses from 3 out of 15 litters examined. | 48 FR 12124; 3/23/83<br>Fiche# OTS0507250                             |

<sup>2</sup>Commercial-grade material similar to Chlorowax 500C® without added stabilizers.

## Results of Testing

| Chemical Name    | CAS No.       | Study Code/Type                       | Protocol/Guideline  | Species                            | Exposure                                | Dose/Concentration   | No. per Group                                  | Results  | Reference                                     |
|------------------|---------------|---------------------------------------|---|------------------------------------|---|--|--|--|---|
| Chlorowax 500C®  | Not available | HERTOXTERA<br>Developmental study     | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | rabbits                            | oral (gavage), day 6-27<br>of gestation | 10, 30, 100 mg/kg/d  | unreported<br>number of<br>pregnant<br>females | The appearance and behavior of the test animals was unaffected by treatment with the test material (Chlorowax 500C). The predominant observations were hair loss on the ventral neck and thorax and reduced amounts of fecal matter (which occurred in all groups). Embryotoxicity at 100 mg/kg/day was evident in 2 test animals with early whole litter reabsorption. The mean numbers of corpora lutea, total implantations, viable fetuses, mean fetal body weight, and fetal sex distribution were not statistically significant when compared to the controls. | 48 FR 34119; 7/2783<br>Fiche# OTS0507252      |
| Chlorowax 500C®  | Not available | HERTOXTERA<br>Developmental study     | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | Mallard duck                       | oral (dietary), 22 wks                  | 28, 166, 1000 ppm  | 20 male;<br>20 female                          | No treatment-related effects from the test material (Chlorowax 500C) were observed in adult test animals on survival, physical condition, body weight, and food consumption. There was a slight decrease as compared to controls from exposure to 1000 ppm in eggshell thickness and 14-day viability. There were no differences found in eggshell thickness or viability at 28 and 166 ppm. In hatchlings, there were no treatment-related effects observed in any of the dose levels tested. The no-observable-effect dietary concentration was 166 ppm.           | 49 FR 44142; 11/2/84<br>Fiche# OTS0507340     |
| Chlorowax 500C®  | Not available | HESTOX<br>Subchronic study            | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | rats, mice                         | oral (gavage), 1x/d; 5<br>d/wk; 13 wks  | 625, 1250, 2500,<br>5000 mg/kg (rats)<br>125, 250, 500, 1000,<br>2000 mg/kg (mice) | 10 male;<br>10 female                          | Rats exposed to the test material (Chlorowax 500C), at 2500 and 5000 mg/kg exhibited decreased weight gain. Clinical signs of decreased activity for 2 hours after dosing were observed in all male and female rats treated with 625, 1250, 2500, and 5000 mg/kg. Enlargement of the liver was observed at all dose levels in both males and females. Male and female mice exposed to 500, 1000, and 2000 mg/kg of test material exhibited decreased weight gain and liver enlargement.  | 49 FR 44124; 11/2/84<br>Fiche# OTS0507337     |
| Chlorowax 500C®  | Not available | HESTOX<br>Subchronic study            | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | rats                               | oral (dietary), 13 wks                  | 10, 100, 625 mg/kg/d   | 15 male;<br>15 female                          | Males exposed to 625 mg/kg/day of the test material (Chlorowax 500C) exhibited a slight decrease in body weight gain and food consumption. An increase in water consumption was observed in both males and females. Slight reductions in hemoglobin and hematocrit were exhibited among high dosed test animals of both sexes. At 100 and 625 mg/kg/day, there were slight changes in total protein, cholesterol, and glucose levels, increased liver weights, and hepatocellular hypertrophy.   | 49 FR 44124; 11/2/84<br>Fiche# OTS0507333     |
| Electrofine S70® | Not available | EECTOX<br>Chronic fish toxicity       | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | Rainbow trout                      | flow-through, 60 days                   | 1.0, 2.1, 3.8 mg/L<br>(measured)   | 30   | The test material (Electrofine S70) was not toxic to the test animals at any of the concentrations tested. There were no mortalities or behavioral changes noted.  | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0507258 |
| Electrofine S70® | Not available | EECTOX<br>Mollusk chronic<br>toxicity | Non-TSCA<br>Protocol/Guideline<br>(see docket # OPTS-42004) | <i>Mytilus edulis</i><br>(mussels) | flow-through, 60 days                   | 0.46, 1.33 mg/L<br>(measured)  | Not specified                                  | There were no mortalities to the test animals exposed to the test material (Electrofine S70). Feeding (filtration) activity was slightly reduced at the higher concentration, but normal at the lower concentration.   | 48 FR 53159;<br>11/25/83<br>Fiche# OTS0507258 |



## Results of Testing

| Chemical Name          | CAS No.       | Study Code/Type   | Protocol/Guideline                                    | Species                       | Exposure                             | Dose/Concentration  | No. per Group        | Results   | Reference                                  |
|------------------------|---------------|---|---|-------------------------------|--------------------------------------|---|----------------------|---|--|
| Electrofine S70®       | Not available | HECTOXTRFM Transformation study                               | Non-TSCA Protocol/Guideline (see docket # OPTS-42004) | mice                          | <i>in vitro</i>                      | 625, 1250, 2500, 5000, 10000 µg/mL (non-activation); 6.25, 12.5, 25, 50, 100 µg/mL (activation) | Not specified        | The test material (Electrofine S70) produced an LC <sub>50</sub> of 10 µg/mL in the absence of metabolic activation and 294 µg/mL in the presence of metabolic activation. In both cases, there were large dose-related increases in transformed colonies   | 47 FR 54160; 12/1/82<br>Fiche# OTS0507248  |
| Electrofine S70®       | Not available | HEGTOXCHRM Mammalian bone marrow chromosomal aberration assay | Non-TSCA Protocol/Guideline (see docket # OPTS-42004) | rats                          | oral (gavage), 1x/d, 5 days          | 0, 500, 1500, 5000 mg/kg/d  | 8 males              | No evidence of increased chromosomal aberrations were noted at any treatment level.   | 49 FR 5187; 2/10/84<br>Fiche# OTS0507331   |
| Electrofine S70®       | Not available | HERTOXTERA Developmental study                                | Non-TSCA Protocol/Guideline (see docket # OPTS-42004) | rats                          | oral (gavage), day 6-19 of gestation | 500, 2000, 5000 mg/kg/d   | 25 pregnant females  | There were no dose-related differences between test animals exposed to the test material (Electrofine S70) in body weight, body weight gain, gestational period, fetal malformations, and development when compared to the controls.  | 49 FR 30114; 7/26/84<br>Fiche# OTS0507334  |
| Electrofine S70®       | Not available | HERTOXTERA Developmental study                                | Non-TSCA Protocol/Guideline (see docket # OPTS-42004) | rabbits                       | oral (gavage), day 6-27 of gestation | 100, 300, 1000 mg/kg/d  | 16 pregnant females  | Exposure to the test material (Electrofine S70) caused no treatment-related effects in maternal appearance, behavior, body weight gain, or in the occurrence of genetic and developmental variations in the treatment groups compared to the controls. No evidence of teratogenicity was noted.   | 48 FR 53159; 11/25/83<br>Fiche# OTS0507257 |
| Methyl isobutyl ketone | 108-10-1      | HECTOXTRFM Transformation assay                               | Non-TSCA Protocol/Guideline (see docket #OPTS-42017)  | mouse BALB/3T3 cells          | <i>in vitro</i>                      | 2.4, 3.6, 4.8 µl/ml (nonactivated)<br>1.0, 2.0, 4.0 µl/ml (activated)                           | Not applicable       | Results indicated that the test material was negative both with and without metabolic activation.   | 50 FR 5421; 2/6/85<br>Fiche# OTS0507470    |
| Methyl isobutyl ketone | 108-10-1      | HEGTOXCHRM Mammalian bone marrow micronucleus assay           | Non-TSCA Protocol/Guideline (see docket #OPTS-42017)  | mice                          | intraperitoneal (i.p.), single dose  | 0.73 ml/kg  | 5 males;<br>5 female | The test material did not induce micronucleated erythrocytes in the test animals.   | 50 FR 5421; 2/6/85<br>Fiche# OTS0507470    |
| Methyl isobutyl ketone | 108-10-1      | HEGTOXDNAF Unscheduled DNA synthesis                          | Non-TSCA Protocol/Guideline (see docket #OPTS-42017)  | rat primary hepatocytes       | <i>in vitro</i>                      | 0.010 to 100 µL/mL  | Not applicable       | No evidence of unscheduled DNA synthesis was noted in any assay.  | 50 FR 5421; 2/6/85<br>Fiche# OTS0507470    |
| Methyl isobutyl ketone | 108-10-1      | HEGTOXMUTA Gene mutations in somatic cells                    | Non-TSCA Protocol/Guideline (see docket #OPTS-42017)  | mouse L5178Y TK +/-           | <i>in vitro</i>                      | 0.32, 0.42, 0.56, 0.75, 1.0, 1.3, 1.8, 2.4, 3.2, 4.2 µg/mL                                      | Not applicable       | Three nonactivated cultures exposed to 1.8, 3.2, and 4.2 µg/mL exhibited mutant frequencies which ranged from 2.0 to 4.8 times the frequency of the solvent control. The total growth ranged from 3 to 58%. A repeat assay failed to show these effects. No effects were seen among activated cultures. The total growth of activated cultures ranged from 23 to 95%. | 50 FR 5421; 2/6/85<br>Fiche# OTS0507470    |
| Methyl isobutyl ketone | 108-10-1      | HEGTOXMUTA Mutagenicity study                                 | Non-TSCA Protocol/Guideline (see docket #OPTS-42017)  | <i>Salmonella typhimurium</i> | <i>in vitro</i>                      | 1.0, 4.0, 5.0, 10.0 µg/plate  | Not applicable       | The test material did not cause a positive response in any of the test strains (TA98, TA100, TA1535, TA1537 and TA1538) with or without metabolic activation.   | 50 FR 5421; 2/6/85<br>Fiche# OTS0507470    |

## Results of Testing

| Chemical Name          | CAS No.  | Study Code/Type                                     | Protocol/Guideline                                   | Species                       | Exposure                            | Dose/Concentration   | No. per Group                         | Results  | Reference                                |
|------------------------|----------|---|--|-------------------------------|-------------------------------------|--|---------------------------------------|--|--|
| Methyl isobutyl ketone | 108-10-1 | HERTOXTERA Developmental study                      | Non-TSCA Protocol/Guideline (see docket #OPTS-42017) | rats, mice                    | inhalation, days 6-15 of gestation  | 0, 300, 1000, 3000 ppm   | unreported number of pregnant females | Rats exposed to 3000 ppm showed maternal toxicity (decreased body weight gain, food consumption, and an increase in relative kidney weight). Mice exposed to 3000 ppm had increased absolute and relative liver weights. At the same dose level, both rats and mice had an increase in the incidence of dead fetuses, reduced fetal weight gain, and reductions in skeletal ossification. At 300 and 1000 ppm, there was no maternal, embryo, or fetal toxicity (including malformations).   | 50 FR 5421; 2/6/85<br>Fiche# OTS0507470  |
| Methyl isobutyl ketone | 108-10-1 | HESTOX Subchronic study                             | Non-TSCA Protocol/Guideline (see docket #OPTS-42017) | rats, mice                    | inhalation, 6 hr/d; 5d/w; 90 days   | 0.50, 250, 1000 ppm  | 14 male;<br>14 female                 | Male rats and mice exposed to 1000 ppm of test material had approximately an 11% increase (compared to controls) in values of absolute and relative (percent of body weight) liver weights. Male mice at 250 ppm had an increase in absolute liver weights, rats did not. Female liver weights both in rats and mice were similar to the controls.   | 49 FR 5187; 2/10/84<br>Fiche# OTS0507467 |
| Methyl ethyl ketone    | 78-93-3  | HECTOXTRFM Transformation assay                     | Non-TSCA Protocol/Guideline (see docket #OPTS-42017) | mouse BALB/3T3 cells          | <i>in vitro</i>                     | 9, 13, 18 µL/mL (non-activated); 6, 8, 10 µL/mL (activated)          | Not applicable                        | Results indicated that the test material was negative both with and without metabolic activation.  | 50 FR 5421; 2/6/85<br>Fiche# OTS0507470  |
| Methyl ethyl ketone    | 78-93-3  | HEGTOXCHRM Mammalian bone marrow micronucleus assay | Non-TSCA Protocol/Guideline (see docket #OPTS-42017) | mice                          | intraperitoneal (i.p.), single dose | 1.90 ml/kg   | 5 males;<br>5 female                  | The test material did not induce micronucleated erythrocytes in the test animals.  | 50 FR 5421; 2/6/85<br>Fiche# OTS0507470  |
| Methyl ethyl ketone    | 78-93-3  | HEGTOXDNAF Unscheduled DNA synthesis                | Non-TSCA Protocol/Guideline (see docket #OPTS-42017) | rat primary hepatocytes       | <i>in vitro</i>                     | 0.0005 to 5.0 µL/plate   | Not applicable                        | No evidence of unscheduled DNA synthesis was noted in any assay.   | 50 FR 5421; 2/6/85<br>Fiche# OTS0507470  |
| Methyl ethyl ketone    | 78-93-3  | HEGTOXMUTA Gene mutations in somatic cells          | Non-TSCA Protocol/Guideline (see docket #OPTS-42017) | mouse L5178Y TK +/-           | <i>in vitro</i>                     | 0.89 to 12 µL/plate (nonactivated); 0.67 to 8.9 µL/plate (activated) | Not applicable                        | No evidence of increased mutation frequencies were noted in any assay.   | 50 FR 5421; 2/6/85<br>Fiche# OTS0507470  |
| Methyl ethyl ketone    | 78-93-3  | HEGTOXMUTA Mutagenicity study                       | Non-TSCA Protocol/Guideline (see docket #OPTS-42017) | <i>Salmonella typhimurium</i> | <i>in vitro</i>                     | 0, 16, 32, 150 µL/plate  | Not applicable                        | No evidence of increased mutant frequency was seen in any of the strains tested (strains TA98, TA100, TA1535, TA1537 and TA1538) with or without activation.   | 50 FR 5421; 2/6/85<br>Fiche# OTS0507470  |
| 4-Nitrophenol          | 100-02-7 | HESTOX Subchronic oral toxicity                     | 40 CFR 798.2675                                      | rat                           | oral (gavage), 1/d for 13 wk        | 0, 25, 70, 140 mg/kg/day   | 20/sex/group                          | Administration of the test substance at 70 mg/kg resulted in increased mortality (1 male, 1 female) and at 140 mg/kg (15 males, 6 females) which appeared to be related to an acute pharmacologic/toxicologic effect exacerbated by repeated dosing. Clinical signs preceding death were pale appearance, languid behavior, prostration, wheezing and dyspnea. No other treatment specific organ pathology, clinical pathology or other effects were noted in the parameters evaluated. The no-effect level was considered to be 25 mg/kg/day. | Fiche# OTS0526338                        |
| Malonitrile            | 109-77-3 | EFTSPT Soil and sediment adsorption isotherm        | 40 CFR 796.2750                                      | Not applicable                | Not specified                       | Not specified  | Not applicable                        | Due to the instability of <sup>14</sup> C-malonitrile in sterile deionized water and the ability to obtain repurified C14-malonitrile by preparative TLC, it was determined that the test compound decomposes too rapidly to successfully conduct an adsorption-desorption test.   | Fiche# OTS0534219                        |

## Results of Testing

| Chemical Name                  | CAS No.   | Study Code/Type                                      | Protocol/Guideline             | Species        | Exposure  | Dose/Concentration                           | No. per Group  | Results   | Reference                                 |
|--------------------------------|-----------|--|--------------------------------|----------------|---|--|----------------|---|---|
| Malonitrile                    | 109-77-3  | HESTOX<br>Subchronic oral<br>toxicity                | 40 CFR 798.2675                | rat            | oral (gavage), 1/d for<br>90 days                           | 0, 0.4, 2, 10 mg/kg/day                      | 10/sex/group   | No significant clinical findings were reported during treatment. There was no treatment related mortality. Occasional salivation was observed in high-dose rats prior to dosing. Body weight of high-dose males at 13 weeks was 6% lower than that of controls. Food consumption was not affected by treatment, but food conversion efficiency was lower in high-dose males as compared to controls. Ophthalmology findings were unremarkable. Significant changes in hematology and clinical chemistry parameters were reported at mid- and high dose levels. These changes were not observed after the recovery period. Absolute and relative liver weight were significantly increased in high-dose groups. This effect was partially reversed by the recovery period. There were no macroscopic findings that suggested gross target organ toxicity attributed to treatment. Hepatocellular hypertrophy was observed in mid- and high-dose males. This was no longer present after the recovery period. | 55 FR 357; 1/4/90<br>Fiche# OTS0526378    |
| Bis(2-chloroethoxy)<br>methane | 111-91-1  | EFADEGHYDR<br>Hydrolysis study                       | 40 CFR 796.3500                | Not applicable | aqueous at pH 3.00,<br>7.06, 11.10, 25 °C, up<br>to 32 days | Not specified                                | Not applicable | No significant hydrolysis was noted at any pH level. A lower limit of half-life was estimated to be at least 2 years at all pH levels. An upper limit could not be estimated.   | 54 FR 7093; 2/16/89<br>Fiche# OTS0526369  |
| Bis(2-chloroethoxy)<br>methane | 111-91-1  | HESTOX<br>Subchronic oral<br>toxicity                | 40 CFR 798.2675                | rats           | oral (gavage), 90 days                                      | 0, 10, 20, 40, 80, 120<br>mg/kg/day          | 10/sex         | Lethality was observed at 80 mg/kg/day and higher. Dose-related effects included decreased body weight (males at 80 mg/kg/day and higher), decreased food intake in high-dose males, histopathological lesions or liver and kidney of males at 20 mg/kg/day, and lesions in the heart, thymus, spleen, bone marrow, brain, and spinal cord at 120 mg/kg/day. The no-adverse effect level was 10 mg/kg/day.  | 55 FR 13956; 4/13/90<br>Fiche# OTS0526337 |
| 4-Chlorobenzotri-<br>chloride  | 5216-25-1 | HESTOX<br>Subchronic toxicity<br>range-finding study | Non-TSCA<br>Protocol/Guideline | rats           | oral (gavage), 2 wks  | 0, 1.25, 12.5, 25, 75,<br>150, 350 mg/kg/day | 6/sex          | Occasional fecal stain and rough coat were seen at 12.5 mg/kg/day. At 25 mg/kg/day and higher, decreased food consumption, decreased weight gain, body weight loss, gastrointestinal disturbance, dehydration, breathing difficulties, ataxia, and tremors were noted. Mortality occurred at 150 mg/kg/day and higher. No adverse effects were noted at 1.25 mg/kg/day.   | 54 FR 33772; 8/16/89<br>Fiche# OTS0526376 |
| 4-Chlorobenzotri-<br>chloride  | 5216-25-1 | HESTOX<br>Subchronic oral<br>toxicity                | 40 CFR 798.2650                | rats           | oral (gavage), 90 days                                      | 0, 1.25, 12.5, 25.0<br>mg/kg/day             | 10/sex         | No mortalities occurred. Decreased weight gain (both sexes at mid- and high-dose) salivation and urine stain (mid- and high-dose males; high-dose females), hematology effects at mid-dose, and lesions of testes (mid- and high-dose) and livers (high-dose females). No effects were seen at 1.25 mg/kg/day.  | 54 FR 33772; 8/16/89<br>Fiche# OTS0526376 |
| Methyl chloride                | 74-87-3   | EFADEGHYDR<br>Hydrolysis study                       | 40 CFR 798.3500                | Not applicable | 25 °C; pH 3, 7, 11  | Not specified                                | Not applicable | The measured rate constants indicate that hydrolysis of methyl chloride under mildly acidic and neutral conditions is essentially negligible. Under basic conditions at pH = 11, hydrolysis apparently takes place - albeit at a slow rate - yielding methanol as a transformation product. Based on hydrolysis characteristics alone, methyl chloride would be expected to persist within normal pH regimes in the aquatic environment.  | 54 FR 33772; 8/16/89<br>OTS0526375        |

## Results of Testing

| Chemical Name                   | CAS No. | Study Code/Type                | Protocol/Guideline | Species        | Exposure                      | Dose/Concentration | No. per Group  | Results   | Reference                                  |
|---------------------------------|---------|--------------------------------|--------------------|----------------|-------------------------------|--------------------|----------------|---|--|
| Dibromomethane                  | 74-95-3 | EFADEGHYDR<br>Hydrolysis study | 40 CFR 798.3500    | Not applicable | 25 °C; pH 3, 7, 11            | Not specified      | Not applicable | Dibromomethane was found to be hydrolytically stable at pH 3 and pH 7. However, moderate degradation was observed at pH 11.   | 54 FR 30460; 7/20/89<br>Fiche# OTS0526374  |
| Bromoform                       | 75-25-2 | EFADEGHYDR<br>Hydrolysis study | 40 CFR 798.3500    | Not applicable | 25 °C ; pH 5, 7, 9;<br>672 hr | 100 ppm            | Not applicable | There was no hydrolytic products formed at a level >10% at any point during the course of the study. The level of inorganic bromide stayed below 0.6 ppm throughout the study. The pH stayed within +/- 0.05 units throughout the test period. The hydrolysis rate for pH 5 is 0.0023 µmole/liter/day and the half-life is 301 days. Bromoform is persistent with respect to hydrolysis for pH 7 and pH 9.            | Study date 3/31/89;<br>Docket# OPTS-42088D |
| Dibromoethane                   | 74-95-3 | EFADEGHYDR<br>Hydrolysis study | 40 CFR 798.3500    | Not applicable | 25 °C ; pH 3, 7, 11           | 150 ppm            | Not applicable | No significant change in dibromomethane concentration was found up to 30-days.  | 54 FR 7093; 2/16/89<br>Fiche# OTS0526368   |
| 1,1-Dichloroethane              | 75-34-3 | EFADEGHYDR<br>Hydrolysis study | 40 CFR 798.3500    | Not applicable | pH 4, 7, 11                   | 1 mM/L             | Not applicable | The test substance was determined to have hydrolytic rate constants of $k_A = 3.07 \times 10^{-1}$ ; $k_B = -4.74 \times 10^{-1}$ ; and $k_N = 1.89 \times 10^{-3}$ .   | Fiche# OTS0526324                          |
| Pentachloroethane               | 76-01-7 | EFADEGHYDR<br>Hydrolysis study | 40 CFR 798.3500    | Not applicable | pH 4, 7, 11                   | 0.02 mM/L          | Not applicable | The test substance was determined to have a very rapid hydrolysis rate at pH 11 (unable to determine hydrolysis rate) and had a half-life of less than 1 minute. The rate constants at pH 7 was determined to be $2.8 \times 10^{-2}$ 1/hr with a half-life of 30.4 hours. At pH 3, the compound appeared virtually unchanged after 334 hours. Tetrachloroethane was identified as the primary decomposition product. | Fiche# OTS0526324                          |
| Dihydrosafrole                  | 94-58-6 | EFADEGHYDR<br>Hydrolysis study | 40 CFR 798.3500    | Not applicable | 25 °C; pH 3, 7, 11            | Not specified      | Not applicable | There was no evidence for the formation of degradation products appearing in chromatograms obtained from the HPLC analyses. No evidence for hydrolysis was detected at any of the pHs tested. Dihydrosafrole appeared hydrolytically stable under the conditions maintained during this study.  | 54 FR 30460; 7/20/89<br>Fiche# OTS0526373  |
| 2,4-Dichloro-phenoxyacetic acid | 94-75-7 | EFADEGHYDR<br>Hydrolysis study | 40 CFR 798.3500    | Not applicable | 25 °C; pH 3, 7, 11            | 21 ppm             | Not applicable | 2,4-D is very stable to hydrolysis at pHs 3, 7 and 11 over a 30-day period. All radioactivity detected during the study at all pHs was identified as 2,4-D only.  | 54 FR 7093; 2/16/89<br>Fiche# OTS0526370   |
| 1,2-Dichlorobenzene             | 95-50-1 | EFADEGHYDR<br>Hydrolysis study | 40 CFR 798.3500    | Not applicable | pH 3, 7, 11                   | 3.9 mg (nominal)   | Not applicable | The test substance was determined to have hydrolytic rate constants of 0.0195, 0.0196, and 0.0153 1/d and half lives of 35.5, 35.4, and 45.4 days for pH 3, 7, and 11, respectively.  | Fiche# OTS0526333                          |
| 1,2,4,5-Tetrachloro-benzene     | 95-94-3 | EFADEGHYDR<br>Hydrolysis study | 40 CFR 798.3500    | Not applicable | pH 3, 7, 11                   | 592 ug/L (nominal) | Not applicable | The test substance was determined to have hydrolytic rate constants of 0.0157, 0.0142, and 0.0165 1/d and half lives of 44.2, 48.9, and 42.1 days for pH 3, 7, and 11, respectively.  | Fiche# OTS0526333                          |

## Results of Testing

| Chemical Name                              | CAS No.    | Study Code/Type                                 | Protocol/Guideline                | Species                        | Exposure                      | Dose/Concentration  | No. per Group        | Results  | Reference                                   |
|--|------------|---|-----------------------------------|--------------------------------|-------------------------------|---|----------------------|--|---|
| 1,3-Dichloro-propanol                      | 96-23-1    | EFTSPT<br>Soil and sediment adsorption isotherm | 40 CFR 796.2750                   | Not applicable                 | Not specified                 | 0.01 M Ca(NO <sub>3</sub> ) <sub>2</sub>  | Not applicable       | The purity of the test substance was 95.3% at initiation and was relatively stable through the adsorption phase with an average of 95.7%, 90.1% and 94.0% for silt loam, clay loam and sandy loam, respectively. Degradation of the test substance was more significant on the soils. Soil extracts analyzed showed 94.5%, 77.0%, and 87.1% for silt loam, clay loam and sandy loam, respectively. The equilibrium pH range was 6.90 to 7.15. The mean C-14-mass balance was 102%, 101% and 96.6% for silt loam, clay loam and sandy loam, respectively. The correlation coefficients obtained for the determined isotherms ranged from 0.8724 to 0.9383 (Freundlich model). | 54 FR 30460; 7/20/89<br>Fiche# OTS0526372   |
| 1,3-Dichloro-propanol                      | 96-23-1    | HESTOX<br>Subchronic oral toxicity              | 40 CFR 798.2650                   | rats                           | oral (gavage), 5 d/wk; 13 wks | 0, 0.1, 1, 10, 100 mg/kg bw/day   | 10/sex               | No adverse effect level = 1 mg/kg/day. Dose related effects at 10 mg/kg/day and higher included increased liver weights in both sexes, histopathologic changes in stomach, kidneys, and liver in males. High-dose rats also showed decreased feed consumption, red blood cell count, hemoglobin, increased total proteins, and nasal lesions.  | 54 FR 48153; 11/21/89<br>Fiche# OTS0526377  |
| Ethyl methacrylate                         | 97-63-2    | EFADEGHYDR<br>Hydrolysis study                  | 40 CFR 798.3500                   | Not applicable                 | 25 °C; pH 3, 7, 11            | 10 µg/mL (ppm)  | Not applicable       | The measured half-life for <sup>14</sup> C-ethyl methacrylate is 410 minutes at pH 11. Since less than 1% hydrolysis occurred at pH 3 or 7 over 28 days, the approximate half-lives calculated from the initial and final concentrations were 4.8 x 10 <sup>3</sup> days at pH 3 and 2.4 x 10 <sup>3</sup> days at pH 7.   | 54 FR 11273; 3/17/89<br>Fiche# OTS0526371   |
| Two tris(iso-propylated phenol)-phosphates | 26967-76-0 | HEADME<br>Dermal study                          | Non-TSCA Protocol/<br>Guideline   | human<br>epidermis             | <i>in vitro</i>               | 261.5 mg/mL TPP, 341.3 mg/mL 2-IDPP ('REOFOS 50'); 30.5 mg/mL TPP, 218.1 mg/mL 2-IDPP (REOLUBE HYD 46') | Not applicable       | The absorption of the major components (i.e., triphenyl phosphate (TPP) and 2-isopropylphenyl diphenyl phosphate (2-IDPP)) of 'REOFOS 50' and REOLUBE HYD 46' through human epidermis was semiquantitatively shown to be in proportion to their formulation proportions. The mean steady state rate of absorption of TPP and 2-IDPP from 'REFOS 50' was 0.90 and 0.54 µg/cm <sup>2</sup> -hr, respectively. The mean steady state rate of absorption of TPP and 2-IDPP from 'REOLUBE HYD 46' was 0.67 and 3.32 µg/cm <sup>2</sup> -hr, respectively.   | 51 FR 6468; 2/24/86,<br>Docket# OPPTS-44014 |
| Tricresyl phosphate                        | 1330-78-5  | HECTOXCARC<br>Carcinogenicity study             | National Toxicology Program (NTP) | F344/N rats                    | diet, 104 wks                 | 0, 75, 150, 300 ppm   | 95 male<br>95 female | No evidence of carcinogenic activity in male or female rats at any dose level. Nonneoplastic lesions associated with exposure included cytoplasmic vacuolization of the adrenal cortex and ovarian interstitial cell hyperplasia in female rats.   | NTP TR-433, Sept. 1994, NTIS PB95-227377    |
| Tricresyl phosphate                        | 1330-78-5  | HECTOXCARC<br>Carcinogenicity study             | NTP                               | B6C3F <sub>1</sub> mice        | diet, 105 wks                 | 0, 60 125, 250 ppm  | 95 male<br>95 female | No evidence of carcinogenic activity in male or female mice at any dose level. Non-neoplastic lesions associated with exposure included increased incidences of clear cell focus, fatty change, and ceroid pigmentation of the liver in male mice and increased severity of ceroid pigmentation of the adrenal cortex in female mice.  | NTP TR-433, Sept. 1994, NTIS PB95-227377    |
| Isopropylphenyl phosphate                  | 28108-99-8 | HEGTOXMUTA<br>SLRL Mutagenicity study           | Non-TSCA Protocol/<br>Guideline   | <i>Drosophila melanogaster</i> | diet                          | 32.5, 75, 150 mg/mL   | Not specified        | The material tested does not induce mutagens in the mature germ cells of <i>Drosophila</i> males when administered in feeding.   | 50 FR 46699; 11/12/85, Docket# OPPTS-44013  |

## Results of Testing

| Chemical Name             | CAS No.       | Study Code/Type                                      | Protocol/Guideline              | Species                       | Exposure  | Dose/Concentration   | No. per Group                     | Results  | Reference                                    |
|---------------------------|---------------|--|---------------------------------|-------------------------------|---|--|-----------------------------------|--|--|
| Isopropylphenyl phosphate | 28108-99-8    | HENEUR<br>Subchronic neuro-toxicity study            | Non-TSCA Protocol/<br>Guideline | domestic hens                 | diet, 91-day  | 0,10, 20, 90, 270<br>mg/kg/d   | 20                                | Birds in the 10 and 20 mg/kg/d dose group were unaffected by treatment. Overall body weight loss and signs of ataxia were noted at doses of 90 or 270 mg/kg/d or 7.5 mg/kg/d TOCP. Significant neurological changes were also observed on histopathologic examination. NOEL - 20 mg/kg/d; LOEL = 90 mg/kg/d.   | Docket# OPPTS-42038A                         |
| Commercial Hexane         | Not available | HEADME<br>Pharmacokinetic assay                      | 40 CFR 795.232<br>(modified)    | rats                          | dermal, 6 hr  | 1.1, 11 mg/cm <sup>3</sup>   | 6/sex                             | The test material was metabolized and excreted within 168 hours of exposure. Exhaled breath and urine were the primary routes of excretion.  | 57 FR 45056; 9/30/92,<br>Docket# OPPTS-44591 |
| Commercial Hexane         | Not available | HEADME<br>Pharmacokinetic assay                      | 40 CFR 795.232<br>(modified)    | rats                          | inhalation, 6 hr/d, 8 days (900 ppm); 6 hr (9000 ppm) | 900, 9000 ppm  | 5/sex (9000 ppm); 6/sex (900 ppm) | The test material was metabolized and excreted within 168 hours of exposure. Exhaled breath and urine were the primary routes of excretion.  | 57 FR 45056; 9/30/92,<br>Docket# OPPTS-44591 |
| Commercial Hexane         | Not available | HECTOXCARC<br>Oncogenicity                           | 40 CFR 798.3300<br>(modified)   | mice                          | whole-body inhalation, 6hr/d, 5d/week, 2 years        | 900, 3000, 9018 ppm  | 50/sex                            | There was no significant difference in survival among any of the control or exposure groups. Hematological and ophthalmoscopic examinations found no signs of any test-related effects. Food consumption in the 9018 ppm group was lower than the controls. Body weight gain and mean body weight were reduced in the 9018 ppm female group. Microscopic examination found an increase in hepatocellular neoplasms (adenoma and carcinoma) and decrease in the severity and a slight decrease in the incidence of cystic endometrial hyperplasia of the uterus among females in the 9018 ppm group. Under the exposure conditions of this study, the test substance was an oncogen in female mice. | 58 FR 40427; 7/28/93,<br>Docket# OPPTS-44600 |
| Commercial Hexane         | Not available | HECTOXCARC<br>Oncogenicity                           | 40 CFR 798.3300<br>(modified)   | rats                          | whole-body inhalation, 6 hr/d, 5 d/wk, 2 years        | 900, 3000, 9000 ppm  | 50/sex/group                      | Under the exposure conditions of this study, commercial hexane was not an oncogen in the rat. Squamous/squamous metaplasia/hyperplasia of the pseudostratified columnar epithelium was seen in a small number of animals and considered to be a localized response indicative of irritation.   | 58 FR 32122; 6/8/93,<br>Docket# OPPTS-44598  |
| Commercial Hexane         | Not available | HEGTOXCHRM<br>Mammalian<br>cytogenetic assay         | 40 CFR 798.5375<br>(modified)   | hamster                       | <i>in vitro</i>                                       | 0.0, 0.015, 0.034, 0.074, 0.123, 0.416 l/ml without metabolic activation; 0.0, 0.014, 0.022, 0.056, 0.118, 0.251 ul/ml with metabolic activation Not specified | Not applicable                    | The two highest exposure levels resulted in high mortality, both with and without metabolic activation. At the other exposure levels, either with or without metabolic activation did not increased the frequency of chromosomal aberrations.  | 55 FR 9504; 3/14/90<br>Fiche# OTS0524324     |
| Commercial Hexane         | Not available | HEGTOXCHRM<br>Mammalian<br>chromosomal<br>aberration | 40 CFR 798.5385<br>(modified)   | rats                          | inhalation (nose only), 6 hr/day; 5 day               | 0, 876, 3249, 8715 ppm   | 5/sex                             | Treatment did not induce chromosomal aberrations in bone marrow cells.   | 55 FR 27303; 7/02/90<br>Fiche# OTS0532896    |
| Commercial Hexane         | Not available | HEGTOXMUTA<br>Reverse mutation<br>assay              | 40 CFR 798.5265)<br>(modified)  | <i>Salmonella typhimurium</i> | <i>in vitro</i>                                       | 0, 600, 1000, 3000, 6000, 9000 ppm   | Not applicable                    | No cytotoxicity resulted at any exposure level evaluated with TA98, TA100, TA1535, TA1537, and TA1538. The test substance did not increase the frequency of histidine revertants, either with or without metabolic activation.   | 54 FR 21117; 8/04/89<br>Fiche# OTS0524322    |

## Results of Testing

| Chemical Name     | CAS No.       | Study Code/Type                                 | Protocol/Guideline         | Species | Exposure   | Dose/Concentration              | No. per Group             | Results  | Reference                                  |
|-------------------|---------------|---|----------------------------|---------|--|---------------------------------|---------------------------|--|--|
| Commercial Hexane | Not available | HENEUR<br>Schedule-controlled operant behavior  | 40 CFR 798.6500 (modified) | rats    | inhalation (nose only), 6 hr                               | 0, 900, 3000, 9000 ppm          | 6/sex                     | Results indicate no significant differences in the rate of responding between control and treated groups.  | 55 FR 9504; 3/14/90<br>OTS524324           |
| Commercial Hexane | Not available | HENEUR<br>Neuropathology                        | 40 CFR 798.6400 (modified) | rats    | inhalation (whole body), 6 hr/d; 5 d/wk; 13 wks            | 0, 900, 3000, 9000 ppm          | 12/sex                    | Results indicate that neuropathological studies at all levels of the neuroaxis proved negative.  | 55 FR 9504; 3/14/90<br>OTS524324           |
| Commercial Hexane | Not available | HENEUR<br>Motor activity                        | 40 CFR 798.6200 (modified) | rats    | inhalation (whole body), 6 hr/d; 5 d/wk; 13 wks            | 0, 900, 3000, 9000 ppm          | 12/sex                    | Results indicated no difference in the motor activity tests among treated and control rats. No abnormal neuropathological changes were observed.   | 55 FR 9504; 3/14/90<br>OTS524324           |
| Commercial Hexane | Not available | HENEUR<br>Functional observational battery      | 40 CFR 798.6050 (modified) | rats    | inhalation (whole body), 6 hr/d; 5 d/wk; 13 wks            | 0, 900, 3000, 9000 ppm          | 12/sex                    | Results indicated no difference in the functional observational battery assessment between treated and control rats. No abnormal neuropathological changes were observed.  | 55 FR 9504; 3/14/90<br>OTS524324           |
| Commercial Hexane | Not available | HERTOXTERA<br>Inhalation developmental toxicity | 40 CFR 798.4350 (modified) | rats    | inhalation, 6 hr/d, gestation days 6-15                    | 0, 900, 3000, 9000 ppm (target) | 25 timed-pregnant females | Maternal toxicity was noted at 3000 ppm and higher (decreased body weight gain and food consumption, treatment-related color changes in lungs at high-dose). No apparent developmental toxicity was noted at any level. The NOEL for maternal toxicity was 900 ppm, and for developmental toxicity, 9000 ppm.  | 54 FR 52449; 12/21/89<br>Fiche# OTS0524323 |
| Commercial Hexane | Not available | HERTOXTERA<br>Inhalation developmental toxicity | 40 CFR 798.4350 (modified) | mouse   | inhalation, 6 hr/d, gestation days 6-15                    | 0, 900, 3000, 9000 ppm          | 30 timed-pregnant females | Maternal toxicity was noted at 3000 ppm and higher (treatment-related color changes in the lungs). Developmental toxicity (treatment-related increased incidence of 2 skeletal variations - bilateral bone islands at the 1st lumbar arch and all intermediate phalanges unossified) was noted at 9000 ppm. The NOEL for maternal toxicity was 900 ppm and for developmental toxicity, 3000 ppm. | 54 FR 52449; 12/21/89<br>Fiche# OTS0524323 |
| Commercial Hexane | Not available | HERTOXTERE<br>Reproductive/fertility effects    | 40 CFR 798.4700 (modified) | rat     | inhalation, from 10 weeks pre-mating through 2 generations | 0, 900, 3000, 9000 ppm          | 24/sex                    | Parental toxicity was noted at 9000 ppm (reduced body weight gain; hyaline droplet nephropathy and tubular basophilia in F0 males); perinatal toxicity at 9000 ppm (decreased weight gain; decreased body weights/litter). The NOEL was 3000 ppm for parents and offspring.  | 56 FR 22715; 5/16/91<br>Fiche# OTS0532897  |

## Results of Testing

| Chemical Name     | CAS No.       | Study Code/Type                             | Protocol/Guideline            | Species        | Exposure           | Dose/Concentration           | No. per Group  | Results   | Reference  |
|-------------------|---------------|---|-------------------------------|----------------|--------------------|------------------------------|----------------|---|--|
| Commercial Hexane | Not available | HESTOX<br>Subchronic inhalation<br>toxicity | 40 CFR 798.2450<br>(modified) | rats           | inhalation, 13 wks | 0, 900, 3000, 9000 ppm       | 10/sex         | No treatment-related mortality, body weight change or alteration in food consumption were seen. Commercial hexane produced a transient, but dose-related increase in lacrimation in female rats. The absolute and relative liver weights in all animals were significantly increased at the highest exposure level, except for the female rat, which did show an upward trend, although not significant. Three out of ten highest-dose male rats were found to have hemorrhage present in the liver,; the severity of these lesions were graded slight. Inflammation was also present in tow out of ten male rat livers in this group, one of which also exhibited hemorrhage. Kidney findings were confined to the male rat where the highest exposure groups showed a statistically y significant increase in organ/body weight and organ/brain weight ratios and renal inflammation was evident in nine of ten animals. In a separate study, these kidney tissues were stained with Mallory's Heidenhain stain and scored for the presence of hydrocarbon nephropathy. Nephrotoxicity scores revealed a grade changed from control to mid dose (27-34) with a sharp increase at the high dose level (82) in male kidneys only. | 55 FR 9504; 3/14/90<br>OTS524324                 |
| Commercial Hexane | Not available | HESTOX<br>Subchronic inhalation<br>toxicity | 40 CFR 798.2450<br>(modified) | mice           | inhalation, 13 wks | 0, 900, 3000, 9000 ppm       | 10/sex         | No treatment-related mortality, body weight change or alteration in food consumption were seen. Commercial hexane produced a transient, but dose-related increase in lacrimation in both sexes. The absolute and relative liver weights in both sexes were significantly increased at the highest exposure level.   | 55 FR 9504; 3/14/90<br>OTS524324                 |
| Cyclohexane       | 110-82-7      | EFMONT<br>Environmental<br>Release Data     | Not applicable                | Not applicable | Not applicable     | Not applicable               | Not applicable | The data submitted by the seven member companies of the CMA's Cyclohexane Panel showed that environmental releases of cyclohexane from their facilities that manufacture, process or use cyclohexane decreased by 52.5% during a 5 year period from 1991 to 1995 and 57% as compared to the total cyclohexane emissions reported in the 1989 Toxic Release Inventory.   | Rcvd 9/19/97,<br>Docket# OPPTS-<br>44644         |
| Cyclohexane       | 110-82-7      | HEADME<br>Dermal absorption                 | 40 CFR 795.226                | rat            | dermal, 6 hrs      | 1 and 100 mg/cm <sup>2</sup> | 4/sex          | Cyclohexane was rapidly excreted after dermal administration. Expired breath was the major route of excretion of radiolabels accounting for ca. 78% of the excreted radiolabel at 1 mg/cm <sup>2</sup> and ca 57% of the excreted radiolabel at 100 mg/cm <sup>2</sup> . Urine was a lesser route of excretion of radiolabel, accounting for ca. 20% at 1 mg/cm <sup>2</sup> and ca. 40% at 100 mg/cm <sup>2</sup> . Essentially no radiolabel was excreted in the feces following dermal administration. The areas under concentration of total radiolabel in blood vs. time curves were ca. 3 times greater at 1 mg/cm <sup>2</sup> and ca. 2 times greater at 100 mg/cm <sup>2</sup> for females than males. Less than 0.1% and less than 0.4% of the dose of cyclohexane at 100 and 1 mg/cm <sup>2</sup> , respectively, remained in the carcass 72 hours after dermal exposure. Thus, neither cyclohexane nor its metabolites would be expected to accumulate after repeated exposure to cyclohexane.  | 61 FR 295624;<br>5/20/96, Docket#<br>OPPTS-44627 |



## Results of Testing

| Chemical Name | CAS No.  | Study Code/Type                                       | Protocol/Guideline  | Species    | Exposure          | Dose/Concentration  | No. per Group | Results  | Reference                                  |
|---------------|----------|---|---------------------|------------|-------------------|---------------------|---------------|--|--|
| Cyclohexane   | 110-82-7 | HEADME<br>Dermal sensitization                        | 40 CFR 795.226      | rat        | bolus intravenous | 10 mg/kg            | 4/sex         | Cyclohexane was rapidly excreted after intravenous administration. Expired breath was the major route of excretion of radiolabels accounting for ca. 70% of the excreted radiolabel. Urine was a lesser route of excretion of radiolabel, accounting for ca. 29%. Essentially no radiolabel was excreted in the feces following intravenous administration. The areas under the concentration of total radiolabel in blood vs. time curves were similar for male and female rats following intravenous administration. Less than 0.4% of the dose of cyclohexane remained in the carcass 72 hours after intravenous exposure. Thus, neither cyclohexane nor its metabolites would be expected to accumulate after repeated exposure to cyclohexane.  | 61 FR 295624; 5/20/96, Docket# OPPTS-44627 |
| Cyclohexane   | 110-82-7 | HEDSEN<br>Dermal sensitization                        | 40 CFR 798.4100     | guinea pig | dermal            | 0.5 mL              | 20            | The modified Buehler Method was used to assess the potential of cyclohexane to produce dermal sensitization in guinea pigs. A 10% concentration of cyclohexane in 95% ethanol was applied to the skin of nine male and eleven female rats for the induction phase. During the induction phase, the response ranged from no redness to very faint redness on the test article animals. Approximately fourteen days after the last induction, a challenge application (10% cyclohexane in acetone) was applied to a naive challenge site. Twenty-four hours after the challenge application of test article, very faint redness was observed in 1/20 animals. The incidence of sensitization among cyclohexane induced and challenged animals was 0/20. Cyclohexane was not a skin sensitizer. | 61 FR 295624; 5/20/96, Docket# OPPTS-44627 |
| Cyclohexane   | 110-82-7 | HENEUR<br>Schedule-controlled operant behavior, acute | 1991 EPA Guidelines | rats       | inhalation, 6 hrs | 500, 2000, 7000 ppm | 10            | Schedule-controlled behavior methods were used to assess the behavioral effects of cyclohexane exposure. The measures of operant performance were fixed ratio response rate, fixed ratio pause duration, fixed interval response rate, and fixed interval index of curvature. On the test day the fixed ratio rate of response for the 7000 ppm group decreased (11%) relative to this group's rate on the day prior to exposure. The effect of 7000 ppm cyclohexane on fixed ratio response rate was transient. No compound-related effects of cyclohexane were detected on the day after exposure nor were any effects apparent for up to two weeks following exposure. The NOEL was 2000 ppm.   | 61 FR 11414; 3/20/96, Docket# OPPTS-44622  |

## Results of Testing

| Chemical Name | CAS No.  | Study Code/Type  | Protocol/Guideline   | Species | Exposure                         | Dose/Concentration  | No. per Group | Results   | Reference  |
|---------------|----------|--|--|---------|----------------------------------|---------------------|---------------|---|--|
| Cyclohexane   | 110-82-7 | HENEUR<br>Neuropathology,<br>subchronic                      | 1991 EPA Guideline<br>for neurotoxicity<br>screening battery | rats    | inhalation, 6 hr/day, 90<br>days | 500, 2000, 7000 ppm | 12/sex        | During exposure to 2000 or 7000 ppm, rats had a diminished response or an absent response to delivery of a punctate alerting stimulus. The diminished or absent alerting response was interpreted to be a compound-related sedative effect. The sedative effect detected during exposures was transient, and no clinical observations of compromised neurological function were detected when the rats were evaluated immediately upon removal from the exposure chambers. The absence of compound-related effects during the Neuropathology evaluation further support the conclusion that cyclohexane-induced sedation during exposure to 2000 and 7000 ppm was transient and reversible. Although the compound-related sedation was transient, it was considered to be toxicologically relevant. Clinical observations revealed no compound-related effects. The NOEL was 500 ppm for both sexes based on the sedation observed at exposure concentrations of 2000 and 7000 ppm.                   | 61 FR 49135; 9/18/96,<br>Docket# OPPTS-<br>44631 |
| Cyclohexane   | 110-82-7 | HENEUR<br>Functional<br>observational battery,<br>subchronic | 1991 EPA Guideline<br>for neurotoxicity<br>screening battery | rats    | inhalation, 6 hr/day, 90<br>days | 500, 2000, 7000 ppm | 12/sex        | During exposure to 2000 or 7000 ppm, rats had a diminished response or an absent response to delivery of a punctate alerting stimulus. The diminished or absent alerting response was interpreted to be a compound-related sedative effect. The sedative effect detected during exposures was transient, and no clinical observations of compromised neurological function were detected when the rats were evaluated immediately upon removal from the exposure chambers. The absence of compound-related effects during the Functional Observational Battery evaluation further support the conclusion that cyclohexane-induced sedation during exposure to 2000 and 7000 ppm was transient and reversible. Although the compound-related sedation was transient, it was considered to be toxicologically relevant. Clinical observations revealed no compound-related effects. The NOEL was 500 ppm for both sexes based on the sedation observed at exposure concentrations of 2000 and 7000 ppm. | 61 FR 49135; 9/18/96,<br>Docket# OPPTS-<br>44631 |

## Results of Testing

| Chemical Name      | CAS No.  | Study Code/Type                             | Protocol/Guideline   | Species                  | Exposure                                      | Dose/Concentration                             | No. per Group  | Results   | Reference  |
|--------------------|----------|---|--|--------------------------|---|--|--|---|--|
| Cyclohexane        | 110-82-7 | HENEUR<br>Motor activity,<br>subchronic     | 1991 EPA Guideline<br>for neurotoxicity<br>screening battery | rats                     | inhalation, 6 hr/day, 90<br>days              | 500, 2000, 7000 ppm                            | 12/sex   | During exposure to 2000 or 7000 ppm, rats had a diminished response or an absent response to delivery of a punctate alerting stimulus. The diminished or absent alerting response was interpreted to be a compound-related sedative effect. The sedative effect detected during exposures was transient, and no clinical observations of compromised neurological function were detected when the rats were evaluated immediately upon removal from the exposure chambers. The absence of compound-related effects during the Motor Activity evaluation further support the conclusion that cyclohexane-induced sedation during exposure to 2000 and 7000 ppm was transient and reversible. Although the compound-related sedation was transient, it was considered to be toxicologically relevant. Clinical observations revealed no compound-related effects. The NOEL was 500 ppm for both sexes based on the sedation observed at exposure concentrations of 2000 and 7000 ppm. | 61 FR 49135; 9/18/96,<br>Docket# OPPTS-<br>44631 |
| Cyclohexane        | 110-82-7 | HERTOXTERA<br>Developmental<br>toxicity     | 40 CFR 798.4350  | rats                     | whole-body inhalation,<br>gestation days 7-16 | 0, 500, 2000, 7000 ppm                         | 25   | No treatment-related differences in fertility, number of resorptions, number of live fetuses, sex ratio, mean fetal weight, or incidences of fetal malformations or variations were observed. No evidence of developmental toxicity was observed at any treatment level. The NOEL was 500 ppm. At 2000 and 7000 ppm, diminished or no response to sound stimulus was noted. The NOEL was 500 ppm.   | 62 FR 8956; 2/27/97<br>Docket# OPPTS-<br>44637   |
| Cyclohexane        | 110-82-7 | HERTOXTERE<br>Reproductive effects          | 40 CFR 798.4700  | rats                     | inhalation, 10 weeks                          | 0, 500, 2000, 7000 ppm                         | 30/sex   | Adverse effects at the 7000 ppm level included statistically significant reductions in mean pup weight in the F1 and F2 generations. No adverse effects were observed at dose levels of 500 ppm and below. The systemic toxicity NOEL was 500 ppm and the reproductive NOEL was 2000 ppm based on decreased pup weights.  | 62 FR 31099; 6/6/97<br>Docket# OPPTS-<br>44640   |
| Cyclohexane        | 110-82-7 | HESTOX<br>Subchronic inhalation<br>toxicity | 40 CFR 798.2450  | mice                     | inhalation, 6 hr/day, 14<br>wks               | 500, 2000, 7000 ppm                            | 20/sex (7000<br>ppm), 10/sex<br>(500 and 2000<br>ppm)          | No compound-related mortalities were observed in the study. No differences in mean body weights, mean body weight gain, food consumption, or food efficiency were observed between treated and control groups. During exposure, mice exposed to 2000 or 7000 ppm had diminished to absent responses to an alerting stimulus and showed clinical signs of toxicity. No compound-related abnormalities were observed during the final ophthalmological examination. No compound-related gross or microscopic changes were observed. The NOEL was 500 ppm in this study.   | 61 FR 49135; 9/18/96,<br>Docket# OPPTS-<br>44631 |
| Cyclohexane        | 110-82-7 | HESTOX<br>Subchronic inhalation<br>toxicity | 40 CFR 798.2450  | rats                     | inhalation, 90 days                           | 0, 500, 2000, 7000 ppm                         | 20/sex (control<br>and 7000 ppm);<br>10/sex (500,<br>2000 ppm) | At the 2000 and 7000 treatment levels, rat had diminished or absent response to an auditory alerting stimulus which was interpreted as a compound-related sedative effect. The sedative effect was transient and no clinical observations of compromised neurological function were detected when rats were removed from the exposure chamber.  | 61 FR 67333;<br>12/20/96, Docket#<br>OPPTS-44634 |
| Tributyl Phosphate | 126-73-8 | EEATOX<br>Daphnid acute toxicity            | 40 CFR 797.1300<br>(modified)                                | <i>Daphnia<br/>magna</i> | flow-through, 48 hr                           | 0, 0.48, 0.96, 2.0, 4.0,<br>8.0 mg/L (nominal) | 20/group   | The 48-hour EC <sub>50</sub> of the test substance was determined to be 2.6 mg/L and the 48-hour no-effect concentration was 0.75 mg/L.   | 55 FR 29411; 7/19/90<br>Fiche# OTS0528316        |

## Results of Testing

| Chemical Name      | CAS No.  | Study Code/Type                                 | Protocol/Guideline         | Species   | Exposure                      | Dose/Concentration                            | No. per Group     | Results  | Reference   |
|--------------------|----------|---|----------------------------|---|-------------------------------|---|-------------------|--|---|
| Tributyl Phosphate | 126-73-8 | EEATOX<br>Acute invertebrate toxicity           | 40 CFR 795.120 (modified)  | gammarus  | flow-through, 96 hr           | ranged from 0.33 to 5.6 mg/L                  | 20 (10/replicate) | The 96-hour LC <sub>50</sub> was 1.7 mg/L. The 96-hour EC <sub>50</sub> value for immobility was 6.2 mg/L. The NOEC was 0.52 mg/L.   | 55 FR 29411; 7/19/90<br>Fiche# OTS0534091               |
| Tributyl Phosphate | 126-73-8 | EEATOX<br>Acute fish toxicity                   | 40 CFR 797.1400 (modified) | rainbow trout                                       | flow-through, 96 hr           | 0, 1.3, 2.5, 5.0, 10, 20 mg/L (nominal)       | 20/group          | The 96-hour LC <sub>50</sub> was calculated to be 13 mg/L. Complete mortality occurred in the 20 mg/L test concentration. Sublethal/behavioral responses (e.g., loss of equilibrium, erratic swimming, labored respiration, surfacing, quiescence, fish on bottom of test chamber and vertical orientation) were noted among the fish in the 10 mg/L test level. The 96-hour no-effect concentration was determined to be 5.0 mg/L based on a lack of sublethal responses at this concentration.   | 55 FR 29411; 7/19/90<br>Fiche# OTS0528315               |
| Tributyl Phosphate | 126-73-8 | EEATOX<br>Algae acute toxicity                  | 40 CFR 797.1050 (modified) | <i>Selenastrum capricornutum</i> (freshwater algae) | static, 96 hr                 | 1.3, 2.5, 5.0, 10, 20 mg/L (nominal)          | Not applicable    | The 96-hour EC <sub>50</sub> was determined to be 4.4 mg/L. The no-effect concentration of the test substance was estimated to be 2.2 mg/L which was based on the absence of affects at this and lower concentrations after 96-hours.  | 55 FR 29411; 6/19/90<br>Fiche# OTS0528318               |
| Tributyl Phosphate | 126-73-8 | EECLIF<br>Fish early life stage                 | 40 CFR 797.1600            | rainbow trout ( <i>Oncorhynchus mykiss</i> )        | flow-through                  | 0.22, 0.39, 0.82, 1.7, and 3.7 mg/L           | Not specified     | No significantly significant reduction in hatchability was detected at any concentration. Length and weight reductions were indicated at 1.7 mg/L. Based on the results of this study, the NOEC and LOEC were determined to be 0.82 and 1.7 mg/L, respectively. The pont estimate MATC was calculated to be 1.2 mg/L.  | 57 FR 3203; 1/29/92.<br>Docket# OPPTS-44580 and 42100B. |
| Tributyl Phosphate | 126-73-8 | EECTOX<br>Chronic invertebrate toxicity         | 40 CFR 797.1330 (modified) | <i>Daphnia magna</i>                                | flow-through, 21 days         | ranged from 0.095 to 2.1 mg/L (mean measured) | 20 (10/replicate) | The 21-day EC <sub>50</sub> (immobilization) was >2.1 mg/L; the NOEC was 0.87 mg/L; the LOEC was 2.1 mg/L (based on growth in length and days to first brood). The 21-day maximum acceptable toxicant concentration (MATC) was >0.87 and <2.1 mg/L.  | Fiche# OTS0534090                                       |
| Tributyl Phosphate | 126-73-8 | EFADEGHYDR<br>Hydrolysis                        | 40 CFR 796.3500            | Not applicable                                      | 30 days at pH 3, 7, 11, 25 °C | 10 ppm  | Not applicable    | No evidence of appreciable hydrolytic degradation of <sup>14</sup> C-tributyl phosphate was detected in any of the buffered solutions. The C14-mass balance ranged from 101.9% to 116.0% of the initial test solution concentrations with a mean of 108%. The thin-layer chromatography plate recoveries ranged from 67.5% to 96.4% with a mean recovery of 85.6%.   | 55 FR 50055; 12/04/90<br>Fiche# OTS0528323              |
| Tributyl Phosphate | 126-73-8 | EFPCEVPRE<br>Vapor pressure                     | 40 CFR 796.1950            | Not applicable                                      | 25 °C                         | Not applicable                                | Not applicable    | Results indicate a mean vapor pressure of the test substance of 2.6 x 10 <sup>-6</sup> mm Hg.  | 55 FR 50055; 12/04/90<br>Fiche# OTS0528324              |
| Tributyl Phosphate | 126-73-8 | EFTSPT<br>Soil and sediment adsorption isotherm | 40 CFR 796.2750            | Not applicable                                      | Not specified                 | Not applicable                                | Not applicable    | The test compound was relatively stable through the adsorption phase with 94.4%, 92.1%, and 94.1% of the C14-activity characterized as parent for soils (silt loam, clay loam, sandy loam), respectively. Soil extracts analyzed by TLC showed that 97.2%, 97.4%, and 96.4% of the C14-recovered was parent material from silt, clay, sandy loams, respectively. The mean C14-mass balance accountability was 95.8%, 101%, and 97.7% for silt, clay, and sandy loams, respectively. The percent adsorbed to silt, clay, and sandy loams was 55.3%, 63.7%, and 47.2%, respectively. | 55 FR 50055; 12/04/90<br>Fiche# OTS0528322              |

## Results of Testing

| Chemical Name      | CAS No.  | Study Code/Type               | Protocol/Guideline         | Species  | Exposure                                    | Dose/Concentration     | No. per Group | Results  | Reference                                |
|--------------------|----------|-------------------------------|----------------------------|----------|---|------------------------|---------------|--|--|
| Tributyl Phosphate | 126-73-8 | HEADME Pharmacokinetics study | 40 CFR 795.228             | rats     | intravenous                                 | 5 mg/kg                | 4/sex         | Recovery of the test substance from urine, feces, expired air, and various organs and tissues was about 90% or above. There was no apparent gender differences in recovery. Results indicate that Phase I metabolism (oxidation and hydrolysis) represented the major biotransformation pathway.   | 59 FR 7784; 2/9/93, Docket# OPPTS-44595  |
| Tributyl Phosphate | 126-73-8 | HEADME Pharmacokinetics study | 40 CFR 795.228             | rats     | dermal, 6-hr                                | 10 and 350 mg/kg       | 4/sex         | Recovery of the test substance from urine, feces, expired air, and various organs and tissues ranged from 66% to 80%. There was no apparent gender differences in recovery. Results indicate that Phase I metabolism (oxidation and hydrolysis) represented the major biotransformation pathway.   | 59 FR 7784; 2/9/93, Docket# OPPTS-44595  |
| Tributyl Phosphate | 126-73-8 | HEADME Pharmacokinetics study | 40 CFR 795.228             | rats     | oral, single                                | 10 and 350 mg/kg       | 4/sex         | Recovery of the test substance from urine, feces, expired air, and various organs and tissues was about 90% or above. There was no apparent gender differences in recovery. Results indicate that Phase I metabolism (oxidation and hydrolysis) represented the major biotransformation pathway.   | 59 FR 7784; 2/9/93, Docket# OPPTS-44595  |
| Tributyl Phosphate | 126-73-8 | HEADME Pharmacokinetics study | 40 CFR 795.228             | rats     | oral, 7 days nonlabeled, then 1 day labeled | 10 and 350 mg/kg       | 4/sex         | Recovery of the test substance from urine, feces, expired air, and various organs and tissues was about 90% or above. There was no apparent gender differences in recovery. Results indicate that Phase I metabolism (oxidation and hydrolysis) represented the major biotransformation pathway.   | 59 FR 7784; 2/9/93, Docket# OPPTS-44595  |
| Tributyl Phosphate | 126-73-8 | HEADME Pharmacokinetics study | 40 CFR 795.228             | minipigs | intravenous                                 | 5 mg/kg                | 2/sex         | Radioactive material was recovered at more than 80% for all dose groups. The test substance was rapidly eliminated primarily via the urine and within the first 6 hr of intravenous exposure, and does not appear to bioaccumulate in the bladder or kidneys. There was no apparent sex differences in this study.   | 59 FR 7784; 2/9/93, Docket# OPPTS-44595  |
| Tributyl Phosphate | 126-73-8 | HEADME Pharmacokinetics study | 40 CFR 795.228             | minipigs | dermal, 6-hr                                | 10 and 350 mg/kg       | 2/sex         | Radioactive material was recovered at about 60% for all dose groups, except the low dose group. The test substance was very poorly absorbed (maximum amount absorbed was about 5% of dose) and it was eliminated mostly via the urine, and does not appear to bioaccumulate in the bladder or kidneys. There was no apparent sex differences in this study.  | 59 FR 7784; 2/9/93, Docket# OPPTS-44595  |
| Tributyl Phosphate | 126-73-8 | HECTOXCARC Oncogenicity       | 40 CFR 798.3300 (modified) | mice     | oral (diet), 1x/d, 18 mo                    | 0, 150, 1000, 3500 ppm | 50/sex/group  | Dose-related, statistically significant increases in liver weights and liver/body and liver/brain weight ratios, relative to control values, were seen in both sexes at the 1000 ppm and the 3500 ppm. Macroscopic and microscopic pathology examinations revealed a statistically significant increased in the incidence of benign liver tumors in the 3500 ppm males and a concurrent increase in the incidence of proliferative lesions of the liver in this group. The incidences of malignant tumors were comparable to controls. Statistical analysis revealed no association between the incidence of benign hepatocellular adenomas and TBP administration in female mice. | 59 FR 17101; 4/11/94 Fiche# OTS0526409-9 |

## Results of Testing

| Chemical Name      | CAS No.  | Study Code/Type                                  | Protocol/Guideline            | Species     | Exposure                                      | Dose/Concentration  | No. per Group  | Results  | Reference  |
|--------------------|----------|--|-------------------------------|-------------|---|---|----------------|--|--|
| Tributyl Phosphate | 126-73-8 | HECTOXCARC<br>Oncogenicity                       | 40 CFR 798.3300<br>(modified) | rats        | oral (diet), 1x/d, 18<br>months               | 0, 200, 700, 3000 ppm   | 50/sex/group   | Dose-related microscopic alterations in the urinary bladder consisted of epithelial hyperplasia and papilloma in both sexes at the 700 and 3000 ppm dose levels. Malignant tumors (transitional cell carcinoma or squamous cell carcinoma) were also present in the high dose (3000 ppm) males and females.  | 59 FR 17101;4/11/94<br>Fiche# OTS0526409-9                 |
| Tributyl Phosphate | 126-73-8 | HEDSEN<br>Dermal sensitization<br>study          | 40 CFR 798.4100               | guinea pigs | dermal, 6 hr, 1x/wk,<br>3 wks                 | 0.31 mL   | 10/sex         | The treatment did not display sensitizing reactions (erythema/eschar and edema scores of 0).   | 55 FR 13956; 4/13/90<br>Fiche# OTS0528314                  |
| Tributyl Phosphate | 126-73-8 | HEGTOXCHRM<br>Mammalian<br>cytogenetic assay     | 40 CFR 798.5375               | hamsters    | <i>in vitro</i>                               | 0.013, 0.025, 0.05, 0.1,<br>0.15 µL/mL (without<br>activation); 0.01, 0.019,<br>0.038, 0.075, 0.15<br>µL/mL (with activation) | Not applicable | No metaphase cells were located for evaluation at 0.15 µL/mL (with and without activation). Toxicity, as measured by a reduction in mitotic index, was approximately 96% at the highest test concentration analyzed (0.1 µL/mL), with and without activation. The four highest test concentrations had no increase in chromosome aberrations either with or without activation. The test substance was concluded to be negative in the CHO cytogenetics assay. | Fiche#<br>OTS0528319                                       |
| Tributyl Phosphate | 126-73-8 | HEGTOXMUTA<br>Gene mutations in<br>somatic cells | 40 CFR 798.5300               | hamsters    | <i>in vitro</i>                               | 0.05, 0.07, 0.08, 0.09,<br>0.11 µL/mL (without<br>activation); 0.06, 0.08,<br>0.10, 0.125, 0.15 µL/mL<br>(with activation)    | Not applicable | Under the conditions of these mutagenicity tests, the test substance was negative in both the absence and presence of exogenous metabolic activation.  | Fiche# OTS0528320  |
| Tributyl Phosphate | 126-73-8 | HENEUR<br>Functional<br>observational battery    | 40 CFR 798.6050               | rats        | oral (gavage), 13 wks                         | 0, 32.5, 100, 325<br>mg/kg/day  | 12/sex/group   | Qualitative and quantitative functional observational battery assessments (grip strength and hind limb splay) did not reveal any significant effects that could be attributed to treatment.  | 56 FR 16333; 4/22/91<br>Fiche# OTS0529309                  |
| Tributyl Phosphate | 126-73-8 | HENEUR<br>Motor activity                         | 40 CFR 798.6200               | rats        | oral (gavage), 13 wks                         | 0, 32.5, 100, 325<br>mg/kg/day  | 12/sex/group   | Results of motor activity tests and gross pathology evaluations were unremarkable.   | 56 FR 16333; 4/22/91<br>Fiche# OTS0529309                  |
| Tributyl Phosphate | 126-73-8 | HENEUR<br>Neuropathology                         | 40 CFR 798.6400               | rats        | oral (gavage), 13 wks                         | 0, 32.5, 100, 325<br>mg/kg/day  | 12/sex/group   | Neuropathological evaluations of microscopical examination of the brain, spinal cord, gastrocnemius muscle, and peripheral structures of the nervous system revealed no neurotoxic effects caused by treatment.  | 56 FR 16333; 4/22/91<br>Fiche# OTS0529309                  |
| Tributyl Phosphate | 126-73-8 | HERTOXTERA<br>Developmental<br>toxicity          | 40 CFR 798.4900<br>(modified) | rats        | oral (gavage)                                 | 0, 188, 375, 750<br>mg/kg/d   | Not specified  | An interim status report summarizes results after completion of the in-life portions of the definitive study. Maternal mortality occurred in the 750 mg/kg/day group. No adverse effects were noted in any developmental or reproduction parameter.  | Fiche# OTS0529383  |
| Tributyl Phosphate | 126-73-8 | HERTOXTERA<br>Developmental<br>toxicity          | 40 CFR 798.4900<br>(modified) | rabbits     | oral (gavage),<br>gestation d 6 through<br>18 | 0, 50, 150, 400 mg/kg/d   | 24 females     | An interim draft of an unaudited completed study indicates maternal toxicity (decreased body weight gain) at 400 mg/kg/day. Increased incidence of resorptions were also noted at 400 mg/kg/day.   | Fiche# OTS0529386  |
| Tributyl Phosphate | 126-73-8 | HERTOXTERE<br>Reproduction/fertility<br>effects  | 40 CFR 798.4700<br>(modified) | rats        | oral (dietary),<br>2 generations              | 0, 100, 300, 1500, 5000<br>ppm  | Not specified  | The in-life portion is completed. Significant decreases were seen in F1 generation body weights, food consumption and organ weights in the high-dose group only. No other information is provided.   | Fiche# OTS0529383<br>Doc# 40-9021232;<br>Fiche# OTS0529391 |

## Results of Testing

| Chemical Name | CAS No. | Study Code/Type            | Protocol/Guideline | Species | Exposure   | Dose/Concentration  | No. per Group | Results   | Reference  |
|---------------|---------|----------------------------|--------------------|---------|--|---|---------------|---|--|
| Isopropanol   | 67-63-0 | HEADME<br>Pharmacokinetics | 40 CFR 795.231     | rats    | iv bolus injection, 168 hr.  | 307 mg/kg   | Not specified | 86% of dose exhaled, with 55% being volatile organics and the balance CO <sub>2</sub> . Less than 5% was excreted in the urine and approximately 1.5% in the feces. The carcass retained less than 4.0% of the dose. Peak blood levels of radiolabel averaged 364 and 329 µg-eq/g for males and females, respectively.  | 56 FR 12202; 3/22/91<br>Fiche# OTS0532880<br>Docket# OPPTS-44566 |
| Isopropanol   | 67-63-0 | HEADME<br>Pharmacokinetics | 40 CFR 795.231     | rats    | gavage, single dose (sacrificed at 72 hr) and multiple dose (sacrificed ensuing 96 hr) | 300 mg/kg (non-toxic); 3000 mg/kg (toxic); 300 mg/kg/d for 8 days (nominal) | Not specified | Exhalation was major route of elimination with 56% and 26% exhaled as radiolabeled organic volatile and CO <sub>2</sub> , respectively, at the low dose and 70% and 16% at the high dose. In the repeat dose study, 56% of the radiolabel was exhaled of which slightly less than 30% was as CO <sub>2</sub> . Urine and feces were minor routes of excretion accounting for <8% and <1%, respectively for the three dosing regimes; carcass retention was <4% of the dose. Peak blood levels for males (females) were 343 (321) µg-eq/g, 2214 (2280) µg-eq/g, and 272 (258) µg-eq/g, respectively, for the three regimes.  | 56 FR 12202; 3/22/91<br>Fiche# OTS0532880<br>Docket# OPPTS-44566 |
| Isopropanol   | 67-63-0 | HEADME<br>Pharmacokinetics | 40 CFR 795.231     | rats    | inhalation (nose only) for 6 hr, 72-hr study   | 476, 4960 ppm   | Not specified | Exhalation was major route of elimination with 83% and 89% of the dose exhaled at low and high dose levels. In the low dose study, 53% (46%) of the exhaled radiolabel as CO <sub>2</sub> , in male (female) rats; 23% of the exhaled dose was CO <sub>2</sub> in the high dose study. Urine and feces were minor routes of excretion accounting for <8% and <2% pf the dose, respectively; carcass retention was <5% of the dose. Peak blood levels for males (females) were 116 (125) µg-eq/g, 1258 (1449) µg-eq/g, respectively, for the two regimes. Principle radiolabeled components in the urine and breath were isopropanol and acetone. Using pooled data from all the pharmacokinetic studies, the half-life for the disappearance of isopropanol from blood was 1-2 hr except for the high-dose oral study which was 4-7 hr. | 56 FR 12202; 3/22/91<br>Fiche# OTS0532880<br>Docket# OPPTS-44566 |
| Isopropanol   | 67-63-0 | HEADME<br>Pharmacokinetics | 40 CFR 795.231     | mice    | iv bolus injection, 96 hr.   | 304.5 mg/kg (male); 313.1 mg/kg (female)                                    | Not specified | 76% of dose exhaled, with 45% being volatile organics and the balance CO <sub>2</sub> . Less than 4% was excreted in the urine and approximately 1.5% in the feces. The carcass retained less than 4.0% of the dose. Peak blood levels of radiolabel averaged 283 and 310 µg-eq/g for males and females, respectively. One radiolabeled metabolite was found in the urine and two in the breath. Radiolabeled metabolites from the breath traps contained isopropanol and acetone or acetone alone.   | 56 FR 12202; 3/22/91<br>Fiche# OTS0532880<br>Docket# OPPTS-44566 |

## Results of Testing

| Chemical Name | CAS No. | Study Code/Type                                  | Protocol/Guideline            | Species                                 | Exposure   | Dose/Concentration   | No. per Group  | Results  | Reference  |
|---------------|---------|--|-------------------------------|---|--|--|----------------|--|--|
| Isopropanol   | 67-63-0 | HEADME<br>Pharmacokinetics                       | 40 CFR 795.231                | mice                                    | whole-body inhalation<br>for 6 hr. 96-hr study                   | 500, 5000 ppm<br>(nominal)   | Not specified  | Exhalation was major route of elimination with 86% of the dose exhaled at the low dose and 92-94% at the high dose. In the low dose study, radiolabeled organic volatiles accounted for 50% of the dose with the balance as CO <sub>2</sub> . In contrast, exhalation of volatile organics accounted for more than three times as much of the absorbed dose than did radiolabeled CO <sub>2</sub> at high dose levels (73% of the absorbed dose). Urine and feces were minor routes of excretion accounting for <7.8% and <2% pf the dose, respectively; carcass retention was about <6.5% of the dose. Peak blood levels for males (females) were 212 (236) µg-eq/g, 2944 (2954) µg-eq/g, respectively, for the two regimes. Three radiolabeled metabolites were found in the urine and two in the breath. Radiolabeled metabolites from the breath traps contained isopropanol and acetone or acetone alone. The half-life for the disappearance of isopropanol from blood generally increased with increasing dose. | 56 FR 12202; 3/22/91<br>Fiche# OTS0532880<br>Docket# OPPTS-44566 |
| Isopropanol   | 67-63-0 | HEGTOXCARC<br>Oncogenicity                       | 40 CFR 798.3300               | rats                                    | inhalation, 6hr/d,<br>5d/week, 104 weeks                         | 500, 2500, 5000 ppm  | 10/sex         | Exposure to isopropanol vapor for 24 months produced clinical signs of toxicity such as hypoactivity, lack of startle reflex, or narcosis at exposure levels of 2500 and 5000 ppm. Urine chemistry changes indicative of kidney damage were noted for males at 2500 ppm and both males and females at 5000 ppm. A number of nonneoplastic lesions were observed in the kidney. The only neoplastic lesion observed for male rats was an increase in interstitial cell adenomas of the testis which was considered to represent marked hyperplasia and was not believed to represent autonomous growth. No increased frequencies of neoplastic lesions were noted for female rats from any isopropanol exposure groups. The NOEL for toxic effects was 500 ppm.   | 59 FR 38472; 7/28/94,<br>Docket# OPPTS-44612                     |
| Isopropanol   | 67-63-0 | HEGTOXCHRM<br>Mammalian BM<br>micronucleus assay | 40 CFR 798.5395<br>(modified) | mice                                    | intraperitoneal<br>injection                                     | 0, 350, 1173, 2500<br>mg/kg  | 15/sex/group   | The test substance did not induce a significant increase in micronuclei in polychromatic erythrocytes at any treatment level under the conditions of this study. Therefore, the test substance is considered negative in the mouse bone marrow micronucleus assay.   | 56 FR 12202; 3/22/91<br>Fiche# OTS0529356                        |
| Isopropanol   | 67-63-0 | HEGTOXMUTA<br>Gene mutations in<br>somatic cells | 40 CFR 798.5300               | Chinese<br>hamster ovary<br>cells (CHO) | <i>in vitro</i>  | 0 (control), and 10<br>concentrations ranging<br>from 0.0098 to 5.0<br>mg/mL | Not applicable | Preliminary cytotoxicity tests indicated that isopropanol was nontoxic to CHO cells at up to 5.0 mg/mL. No evidence of increased mutant frequencies over controls was noted, with or without activation.   | 55 FR 25366; 6/21/90<br>Fiche# OTS0525977                        |
| Isopropanol   | 67-63-0 | HENEUR<br>Developmental<br>neurotoxicity screen  | 40 CFR 795.250                | rats                                    | oral (gavage),<br>gestation day 6<br>through postnatal day<br>21 | 0, 200, 700, 1200<br>mg/kg/d   | 35 females     | Maternal toxicity (death of 1/35) occurred at 1200 mg/kg/day. No evidence of developmental neurotoxicity was observed at any dose tested. The NOAEL for maternal toxicity was 700 mg/kg/day and for developmental neurotoxicity was 1200 mg/kg/day.  | Fiche# OTS0532882  |



## Results of Testing

| Chemical Name | CAS No. | Study Code/Type                                 | Protocol/Guideline            | Species | Exposure  | Dose/Concentration                | No. per Group                                | Results   | Reference                                     |
|---------------|---------|---|-------------------------------|---------|---|-----------------------------------|--|---|---|
| Isopropanol   | 67-63-0 | HENEUR<br>Functional<br>observational battery   | 40 CFR 798.6050<br>(modified) | rats    | inhalation, 6 hr                                  | 0, 500, 1500, 5000,<br>10,000 ppm | 25/sex/group                                 | Statistically significant FOB changes were observed for most of the parameters evaluated at 1- and 6- hour periods for animals in the 10,000 ppm group. Exposure-related changes in some FOB parameters were observed in animals in the 5000 ppm group 1 hour after exposure. Based on the results of the study, exposure of male and female rats to 5000 and 10,000 ppm produced transient, concentration-related narcosis and/or central nervous system sedation. | Fiche# OTS0529356                             |
| Isopropanol   | 67-63-0 | HENEUR<br>Functional<br>observational battery   | 40 CFR 798.6050<br>(modified) | mice    | inhalation, 6 hr/d, 5<br>d/wk, 14 weeks           | 0, 100, 500, 1500, 5000<br>ppm    | 10/sex/group                                 | Neurobehavioral evaluations indicated no changes in the functional observational battery.   | Fiche# OTS0529356                             |
| Isopropanol   | 67-63-0 | HENEUR<br>Functional<br>observational battery   | 40 CFR 798.6050<br>(modified) | rats    | inhalation, 6 hr/d, 5<br>d/wk, 14 weeks           | 0, 100, 500, 1500, 5000<br>ppm    | 25/sex/group,<br>except 10/sex at<br>100 ppm | Neurobehavioral evaluations indicated no changes in the functional observational battery.   | Fiche# OTS0529356                             |
| Isopropanol   | 67-63-0 | HENEUR<br>Motor activity                        | 40 CFR 798.6200<br>(modified) | rats    | inhalation, 6 hr/d, 5<br>d/wk, 14 weeks           | 0, 100, 500, 1500, 5000<br>ppm    | 25/sex/group,<br>except 10/sex at<br>100 ppm | Increased motor activity for female rats in the 5000 ppm group was noted at weeks 9 and 13.   | Fiche# OTS0529356                             |
| Isopropanol   | 67-63-0 | HENEUR<br>Motor activity                        | 40 CFR 798.6200<br>(modified) | rats    | inhalation, 6 hr                                  | 0, 500, 1500, 5000,<br>10,000 ppm | 25/sex/group                                 | Concentration-related decreases in mean motor activity were observed for males in the 1500, 5000, and 10,000 ppm and females in the 5000 and 10,000 ppm groups. Based on the results of the study, exposure of male and female rats to 5000 and 10,000 ppm produced transient, concentration-related narcosis and/or central nervous system sedation  | Fiche# OTS0529356                             |
| Isopropanol   | 67-63-0 | HENEUR<br>Neuropathology                        | 40 CFR 798.6400<br>(modified) | rats    | inhalation, 6 hr/d, 5<br>d/wk, 14 wks             | 0, 100, 500, 1500, 5000<br>ppm    | 25/sex/group,<br>except 10/sex at<br>100 ppm | Neuropathologic examination revealed no exposure-related lesions in the central or peripheral nervous system.   | Fiche# OTS0529356                             |
| Isopropanol   | 67-63-0 | HERTOXTERA<br>Developmental<br>toxicity         | 40 CFR 798.4900               | rats    | oral (gavage),<br>gestation day 6-15              | 0, 400, 800, 1200<br>mg/kg/d      | 25 females                                   | Maternal toxicity was observed at 800 and 1200 mg/kg/day (mortality: 1 at mid-dose; and 2 at high-dose); reduced maternal weight gain at 1200 mg/kg/day (possibly due to reduced gravid uterine weight). Fetotoxicity (reduced fetal body weight and litter weight) occurred at 800 and 1200 mg/kg/day.   | 55 FR 53348;<br>12/28/90<br>Fiche# OTS0529355 |
| Isopropanol   | 67-63-0 | HERTOXTERA<br>Developmental<br>toxicity         | 40 CFR 798.4900               | rabbits | oral (gavage),<br>gestation day 6-18              | 0, 120, 240, 480<br>mg/kg/d       | 15 females                                   | Maternal toxicity was observed at 480 mg/kg/day (decreased body weight and food consumption, rupture of peripheral capillaries in the ear of 1 doe, cyanosis and lethargy in another). No evidence of embryotoxicity, fetotoxicity, or teratogenicity was seen at any level.  | 55 FR 53348;<br>12/28/90<br>Fiche# OTS0529355 |
| Isopropanol   | 67-63-0 | HERTOXTERE<br>Reproductive/fertility<br>effects | 40 CFR 798.4700               | rats    | oral (gavage),<br>continuous for 2<br>generations | 0, 100, 500, 1000<br>mg/kg/d      | 30/sex                                       | Summary information indicated that increased maternal weight gain was observed in the mid- and high-dose groups, but not the low-dose group. A significant increase in post-weaning pup mortality in high-dose animals was noted (generation not specified). The NOAEL for maternal effects was 100 mg/kg/day and for reproductive toxicity $\geq$ 1000 mg/kg/day. No other information was provided in this report.  | 57 FR 23227; 6/02/92<br>Fiche# OTS0532880     |

## Results of Testing

| Chemical Name                  | CAS No.  | Study Code/Type   | Protocol/Guideline | Species                      | Exposure  | Dose/Concentration                                   | No. per Group              | Results   | Reference                                    |
|--------------------------------|----------|---|--------------------|------------------------------|---|--|----------------------------|---|--|
| Isopropanol                    | 67-63-0  | HESTOX<br>Subchronic inhalation toxicity                                | 40 CFR 798.2450    | rats and mice                | inhalation, 6 hr/d, 5 d/wk, 13 wks  | 0, 500, 1500, 5000 ppm                               | 25 rats/sex or 10 mice/sex | This summary report indicated that no significant histopathologic effects were noted on reproductive organs. No other information was provided.   | 56 FR 2202; 3/22/91<br>Fiche# OTS0532880     |
| <i>tert</i> -Amyl methyl ether | 994-05-8 | HEADME<br>Pilot study for Metabolism, Distribution and Pharmacokinetics | 40 CFR 795.230     | rats                         | inhalation, nose-only, single, 6 hours  | 2500 ppm   | 4                          | Over 95% of radioactivity recovered for up to 7 days was excreted by 48 hours after exposure. The majority of radioactivity was found in charcoal traps (44% of total recovered) and in urine (51%), with a minor amount in feces (1%) and KOH traps (3%). Less than 0.5% of the total recovered radioactivity was in the carcass.  | 62 FR 51858; 10/3/97;<br>Docket# OPPTS-44643 |
| <i>tert</i> -Amyl methyl ether | 994-05-8 | HEADME<br>Pharmacokinetics, blood                                       | 40 CFR 795.230     | mice                         | inhalation, nose-only, single, 6 hours  | 100, 500, 2500 ppm                                   | Not reported               | The concentration of TAME in blood following exposure to 100 ppm was 1.5 µg/ml. The half-life was between 13 and 48 minutes. Acetone was elevated above background levels at all exposure concentrations. Acetone elevation at 500 or 2500 ppm was up to six times greater than that measured after the 100 ppm exposure.   | 62 FR 51858; 10/3/97;<br>Docket# OPPTS-44643 |
| <i>tert</i> -Amyl methyl ether | 994-05-8 | HEADME<br>Pharmacokinetics, blood                                       | 40 CFR 795.230     | rats                         | inhalation, nose-only, single, 6 hours  | 100, 500, 2500 ppm                                   | Not reported               | The concentration of TAME in blood following exposure to 100 ppm was 3 µg/ml. The half-life was between 33 and 84 minutes. Acetone was elevated above background levels at all exposure concentrations.   | 62 FR 51858; 10/3/97;<br>Docket# OPPTS-44643 |
| <i>tert</i> -Amyl methyl ether | 994-05-8 | HEADME<br>Metabolism and distribution                                   | 40 CFR 795.230     | rats                         | inhalation, nose-only, single, 6 hours; additional group whole-body inhalation, 5 days. | 100, 500, 2500 ppm (nose-only); 500 ppm (whole-body) | Not reported               | For inhalation exposures, rats had a linear response for the total (0-48 hr following exposure termination) exhaled TAME and <i>tert</i> -amyl alcohol (TAA) as a function of exposure concentration. A decrease in the amount (0-48 hr) of expired TAME was observed for rats, but not mice, following 5 days of inhalation exposure to 500 ppm TAME as compared with 1 day of exposure. | 62 FR 51858; 10/3/97;<br>Docket# OPPTS-44643 |
| <i>tert</i> -Amyl methyl ether | 994-05-8 | HEADME<br>Metabolism and distribution                                   | 40 CFR 795.230     | mice                         | inhalation, nose-only, single, 6 hours; additional group whole-body inhalation, 5 days. | 100, 500, 2500 ppm (nose-only); 500 ppm (whole-body) | Not reported               | For inhalation exposures, mice had an increase in exhaled TAME and TAA (normalized by body weight and exposure concentration) observed with an increase in exposure concentration. A decrease in the amount (0-48 hr) of expired TAME was observed for rats, but not mice, following 5 days of inhalation exposure to 500 ppm TAME as compared with 1 day of exposure.                    | 62 FR 51858; 10/3/97;<br>Docket# OPPTS-44643 |
| <i>tert</i> -Amyl methyl ether | 994-05-8 | HEADME<br>Metabolism and distribution                                   | 40 CFR 795.230     | rats                         | oral, gavage  | 10, 100 mg/kg  | Not reported               | Female rats had an increase in exhaled TAME (normalized by body weight and amount administered) following gavage at the high dose, as compared with the low dose.   | 62 FR 51858; 10/3/97;<br>Docket# OPPTS-44643 |
| <i>tert</i> -Amyl methyl ether | 994-05-8 | HEADME<br>Metabolism and distribution                                   | 40 CFR 795.230     | mice                         | oral, gavage  | 20, 100 mg/kg  | Not reported               | Male and female mice had an increase in exhaled TAME (normalized by body weight and amount administered) following gavage at the high dose, as compared with the low dose.  | 62 FR 51858; 10/3/97;<br>Docket# OPPTS-44643 |
| <i>tert</i> -Amyl methyl ether | 994-05-8 | HEGETOXCHRM<br>Mutagenicity; Chromosomal aberrations                    | 40 CFR 798.5375    | Chinese hamster, ovary cells | <i>in-vitro</i>   | 313-5000 µg/mL                                       | Not applicable             | The test substance was positive for mutagenic effect in the S-9 activated system.   | 61 FR 42611; 8/16/96;<br>Docket# OPPTS-44629 |

## Results of Testing

| Chemical Name                  | CAS No.  | Study Code/Type                                | Protocol/Guideline | Species                      | Exposure                                 | Dose/Concentration              | No. per Group                        | Results  | Reference                                 |
|--------------------------------|----------|--|--------------------|------------------------------|--|---------------------------------|--------------------------------------|--|---|
| <i>tert</i> -Amyl methyl ether | 994-05-8 | HEGETOXMUTA<br>Mutagenicity:<br>CHO/HGRT assay | 40 CFR 798.5300    | Chinese hamster, ovary cells | <i>in-vitro</i>                          | 1000 to 5000 µg/mL              | Not applicable                       | The test substance was negative in the CHO/HGPRT mutagen assay.  | 61 FR 42611; 8/16/96, Docket# OPPTS-44629 |
| <i>tert</i> -Amyl methyl ether | 994-05-8 | HENEUR<br>Neurotoxicity screen                 | 40 CFR 795.247     | rats                         | inhalation, whole-body, 5 d/wk, 13 weeks | 0, 250, 1500, 3500 ppm          | 51 (0, 3500 ppm); 41 (250, 1500 ppm) | Exposure to 3500 ppm resulted in neurological effects including depression of central nervous system activity and neuromuscular impairment, one hour after acute exposure; these effects were no longer evident 6 and 24 hours after acute exposure and were not seen after repeated exposure to the test substance. The NOEL for acute neurobehavioral effects was 250 ppm in males and 1500 ppm in females. The NOEL for subchronic neurotoxicity was 3500 ppm in both males and females.  | 62 FR 51858; 10/3/97; Docket# OPPTS-44643 |
| <i>tert</i> -Amyl methyl ether | 994-05-8 | HERTOXTERA<br>Developmental toxicity           | 40 CFR 870.3700    | rats                         | inhalation, 6 hr/d, gestation day 6 - 19 | 0, 250, 1500, 3500 ppm (target) | 25                                   | No dams dies, aborted, or delivered early. Maternal body weight was significantly reduced at 3500 ppm. Treatment-related clinical observations included ataxia, dazed appearance, lethargy, eye(s) squinting or closed, and slow respiration at 3500 ppm, and lethargy and piloerection at 1500 ppm. Developmental toxicity was present at 3500 ppm, specifically reduced fetal body weights per litter. There were no treatment-related changes in the incidence or severity of fetal external, visceral, skeletal or total malformations or variations in this study. The NOAEL for maternal toxicity was 250 ppm and for developmental toxicity was 1500 ppm under the conditions of this study.                      | 62 FR 18350; 4/15/97, Docket# OPPTS-44639 |
| <i>tert</i> -Amyl methyl ether | 994-05-8 | HERTOXTERA<br>Developmental toxicity           | 40 CFR 870.3700    | mice                         | inhalation, 6 hr/d, gestation day 6 - 16 | 0, 250, 1500, 3500 ppm (target) | 25                                   | Four dams died at 3500 ppm. Treatment-related clinical observations included mortality, ataxia, prone positioning, gasping, rough coat, lethargy, eye(s) squinted, head tremors and slow respiration at 3500 ppm, and eye(s) half closed and head tremors at 1500 ppm. Developmental toxicity was present at 3500 ppm, specifically significantly increased incidence of late fetal deaths, significantly reduced fetal body weights per litter, and increased incidences of cleft palate and enlarged lateral ventricles of the cerebrum. At 1500 ppm, fetuses also exhibited an increased incidence of cleft palate. The NOAEL for maternal and developmental toxicity was 250 ppm under the conditions of this study. | 62 FR 18350; 4/15/97, Docket# OPPTS-44639 |
| <i>tert</i> -Amyl methyl ether | 994-05-8 | HERTOXTERE<br>Reproduction and Fertility       | 40 CFR 870.3800    | rats                         | inhalation                               |                                 |                                      |  | 63 FR 25040; 5/6/98, Docket# OPPTS-44648  |

## Results of Testing

| Chemical Name                  | CAS No.  | Study Code/Type  | Protocol/Guideline  | Species | Exposure                                       | Dose/Concentration        | No. per Group                        | Results   | Reference                                 |
|--------------------------------|----------|--|---|---------|--|---------------------------|--------------------------------------|---|---|
| <i>tert</i> -Amyl methyl ether | 994-05-8 | HESTOX<br>90-Day Subchronic toxicity                   | 40 CFR 798.2450<br>(Amended to include mitogenesis, special staining and immunochemistry) | rats    | inhalation, whole-body, 5 d/wk, 13 weeks       | 0, 250, 1500, 3500 ppm    | 51 (0, 3500 ppm); 41 (250, 1500 ppm) | Exposure to 3500 ppm resulted in low incidence of mortality (2/102), abnormal clinical signs (lethargy and prostration), decreased body weight and body weight gain, effects on hematology (increased platelet counts), effects on clinical chemistry (increases in protein, albumin and globulin), and effects on organ weights. Microscopic examination revealed increased intracytoplasmic eosinophilic/hyaline droplets in proximal convoluted tubules in male kidneys which contained alpha-2u-globulin immunoreactivity. There was also increased kidney proliferation and increased neuropathy. Based on these findings, the NOEL for female rats was 250 ppm and for male rats was not established. | 62 FR 51858; 10/3/97; Docket# OPPTS-44643 |
| <i>tert</i> -Amyl methyl ether | 994-05-8 | HESTOX<br>90-Day Subchronic toxicity                   | 40 CFR 798.2450<br>(Amended to include mitogenesis, special staining and immunochemistry) | mice    | inhalation, whole-body, 5 d/wk, 13 weeks       | 0, 250, 1500, 2500 ppm    | 46 (0, 2500 ppm); 36 (250, 1500 ppm) | Exposure to 2500 ppm resulted in mortality, abnormal clinical signs (prostration, lethargy, decreased activity), effects on clinical chemistry and increased absolute and relative liver weights. Cell proliferations studies in the liver showed increased labeling index of hepatocytes and there was microscopic evidence of centrilobular hepatocellular hypertrophy in males and females. The NOEL for males was 250 ppm and the NOEL for females was not established.   | 62 FR 51858; 10/3/97; Docket# OPPTS-44643 |
| Acetone                        | 67-64-1  | HENEUR<br>Schedule Controlled Operant Behavior         | 1991 EPA Guideline<br>EPA 540/09-01-123   | rat     | inhalation, 6 hr/d, 5 d/wk, 13-weeks           | 0, 1000, 2000, 4000 ppm   | 10/males/group                       | There were no treatment-related effects of acetone on clinical observations and operant performance.  | 62 FR 42123; 8/5/97 Docket# OPPTS-44642   |
| <i>n</i> -Amyl acetate         | 628-63-7 | HENEUR<br>Functional Observational Battery, acute      | 1991 EPA Guideline<br>EPA 540/09-01-123   | rat     | whole-body inhalation, 6 hr                    | 0, 500, 1500, or 3000 ppm | 10/sex/dose                          | No overt clinical signs of toxicity or changes in body weight, FOB evaluations were found under the conditions of this study. The NOEL was at least 3000 ppm.   | 62 FR 11183; 3/11/97, Docket# OPPTS-44638 |
| <i>n</i> -Amyl acetate         | 628-63-7 | HENEUR<br>Motor Activity, acute                        | 1991 EPA Guideline<br>EPA 540/09-01-123   | rat     | whole-body inhalation, 6 hr                    | 0, 500, 1500, or 3000 ppm | 10/sex/dose                          | No overt clinical signs of toxicity or changes in body weight, automated motor activity measurements were found under the conditions of this study. The NOEL was at least 3000 ppm.   | 62 FR 11183; 3/11/97, Docket# OPPTS-44638 |
| <i>n</i> -Amyl acetate         | 628-63-7 | HENEUR<br>Functional Observational Battery, subchronic | 1991 EPA Guideline<br>EPA 540/09-01-123   | rat     | whole-body inhalation 6 hr/d, 5 d/wk, 13-weeks | 0, 300, 600, 1200 ppm     | 10/sex/group                         | During the first two weeks there was a reduction in activity during exposure to 600 and 1200 ppm. This effect did not persist after the end of exposure. No dose-related changes were found in FOB evaluations under the conditions of this study. For the acute sedative effects the LOEL was 600 ppm and the NOEL was 300 ppm. [EPA]  | 63 FR 1464, 1/9/98, Docket# OPPTS-44645   |
| <i>n</i> -Amyl acetate         | 628-63-7 | HENEUR<br>Motor Activity, subchronic                   | 1991 EPA Guideline<br>EPA 540/09-01-123   | rat     | whole-body inhalation 6 hr/d, 5 d/wk, 13-weeks | 0, 300, 600, 1200 ppm     | 10/sex/group                         | No changes in automated motor activity measurements were found under the conditions of this study. The NOEL was at least 1200 ppm. [EPA]  | 63 FR 1464, 1/9/98, Docket# OPPTS-44645   |
| <i>n</i> -Amyl acetate         | 628-63-7 | HENEUR<br>Neuropathology, subchronic                   | 1991 EPA Guideline<br>EPA 540/09-01-123   | rat     | whole-body inhalation 6 hr/d, 5 d/wk, 13-weeks | 0, 1200 ppm               | 5/sex/group                          | Microscopic evaluation of the brain and spinal cord from the high concentration rats revealed no morphological differences from the control rats; thus there were no compound-related changes. The NOEL was at least 1200 ppm. [EPA]  | 63 FR 1464, 1/9/98, Docket# OPPTS-44645   |

## Results of Testing

| Chemical Name           | CAS No.  | Study Code/Type  | Protocol/Guideline   | Species    | Exposure                     | Dose/Concentration           | No. per Group   | Results  | Reference  |
|-------------------------|----------|--|--|------------|------------------------------|------------------------------|---|--|--|
| <i>n</i> -Butyl acetate | 123-86-4 | HEADME<br><i>in vivo</i> Hydrolysis                    | non-TSCA<br>Protocol/Guideline<br>(see docket #OPPTS-<br>42134G) | rat (male) | intravenous                  | 30.2 mg/kg (in 0.9%<br>NaCl) | 32  | Liquid scintillation analysis following dose revealed rapid systemic distribution of the dose and very rapid elimination from the body. It was very rapidly eliminated from blood ( $t_{1/2}$ = 0.41 min) and was only detected in brain tissue at low concentrations in first 2.5 min after dosing. Hydrolysis in blood and brain is estimated to be 99% complete by 2.7 min at this dose level. <i>n</i> -Butanol, the hydrolysis product, was found in higher concentrations in both the blood and brain but was rapidly eliminated ( $t_{1/2}$ = 1.0 - 1.2 min). <i>n</i> -Buteric acid was present at low concentrations in blood and declined slowly after dosing; it was largely undetected in brain tissue.  | 62 FR 89552/27/97<br>Docket# OPPTS-<br>44636     |
| <i>n</i> -Butyl acetate | 123-86-4 | HENEUR<br>Motor Activity,<br>subchronic                | 1991 EPA Guideline<br>EPA 540/09-01-123                          | rat        | inhalation, 6 hrs, 14<br>wks | 0, 500, 3000, 6000 ppm       | 10/sex (500 and<br>1500 ppm),<br>15/sex (3000<br>ppm) | No spontaneous mortality occurred during the study. Exposures to <i>n</i> -butyl acetate vapors resulted in acute, transient signs of reduced activity levels on a daily basis at 1500 and 3000 ppm, but no evidence of a cumulative effect on activity during the 14 week exposure. There was no evidence of neurotoxicity based on motor activity. The NOEL was 3000 ppm for this study.   | 61 FR 11414; 3/20/96,<br>Docket#. 44622          |
| <i>n</i> -Butyl acetate | 123-86-4 | HENEUR<br>Functional Obser-<br>vational Battery, acute | 1991 EPA Guideline<br>EPA 540/09-01-123                          | rat        | inhalation, 6hrs             | 0, 500, 3000, 6000 ppm       | 10/sex/dose   | Concentrations of 1500, 3000, and 6000 ppm reduced activity and response to stimulus during exposure. Sialorrhea was observed in treated male rats, but only occasionally in treated female rats. Tearing was also noted occasionally in treated female rats. No deaths were noted during exposure and no clinical signs of toxicity noted at any time post-exposure. In the Functional Observational Battery (FOB) on day 0, the hair coat scores of the 6000 ppm group were significantly higher than in controls. Forelimb grip strength for females in the 3000 ppm group was significantly higher on day 0, than for the control group. There were no differences in hair coat scores and forelimb grip strength on days 7 and 14. The differences in mean body weight between treated and control groups were less than 10%. No treatment-related gross lesions were noted at necropsy. The NOEL for changes that occurred after animals were removed from vapor was 1500 ppm. | 59 FR 54193;<br>10/28/94, Docket#<br>OPPTS-44613 |
| <i>n</i> -Butyl acetate | 123-86-4 | HENEUR<br>Schedule Controlled<br>Operant Behavior      | 1991 EPA Guideline<br>EPA 540/09-01-123                          | rat        | inhalation, 6 hrs, 13<br>wks | 0, 500, 1500, 3000 ppm       | 10/sex/dose   | No spontaneous mortality occurred during the study. Exposures to <i>n</i> -butyl acetate vapors resulted in acute, transient signs of reduced activity levels on a daily basis at 1500 and 3000 ppm in male rats, but no evidence of a cumulative effect on activity during the 13 week exposure. There was no evidence of neurotoxicity based on schedule-controlled operant behavior. The NOEL was 3000 ppm for this study.  | 61 FR 11414; 3/20/96,<br>Docket#. 44622          |

## Results of Testing

| Chemical Name           | CAS No.  | Study Code/Type  | Protocol/Guideline                      | Species | Exposure                     | Dose/Concentration      | No. per Group                                   | Results   | Reference                                  |
|-------------------------|----------|--|---|---------|------------------------------|-------------------------|---|---|--|
| <i>n</i> -Butyl acetate | 123-86-4 | HENEUR<br>Motor Activity, acute                        | 1991 EPA Guideline<br>EPA 540/09-01-123 | rat     | inhalation, 6 hrs            | 0, 1500, 3000, 6000 ppm | 10/sex/dose                                     | Activity and response to stimulus were reduced during all exposure levels. Sialorrhea was observed in treated male rats, but only occasionally in treated female rats. Tearing was also noted occasionally in treated female rats. No deaths were noted during exposure and no clinical signs of toxicity noted at any time post-exposure. Mean total motor activity and total ambulations on day 0 in the 3000 and 6000 ppm groups were significantly lower than in the control group. These differences were on days 1, 7, or 14. There was no overall effect on activity during exploratory behavior or habituation periods. No treatment-related gross lesions were noted at necropsy. The NOEL for changes that occurred after animals were removed from vapor was 1500 ppm. | 59 FR 54193; 10/28/94, Docket# OPPTS-44613 |
| <i>n</i> -Butyl acetate | 123-86-4 | HENEUR<br>Neuropathology, subchronic                   | 1991 EPA Guideline<br>EPA 540/09-01-123 | rat     | inhalation, 6 hrs, 14 wks    | 0, 500, 1500, 3000 ppm  | 10/sex (500 and 1500 ppm),<br>15/sex (3000 ppm) | No spontaneous mortality occurred during the study. Exposures to <i>n</i> -butyl acetate vapors resulted in acute, transient signs of reduced activity levels on a daily basis at 1500 and 3000 ppm, but no evidence of a cumulative effect on activity during the 14 week exposure. There was no evidence of neurotoxicity based on neuropathology. The NOEL was 3000 ppm for this study.  | 61 FR 11414; 3/20/96, Docket#. 44622       |
| <i>n</i> -Butyl acetate | 123-86-4 | HENEUR<br>Functional Observational Battery, subchronic | 1991 EPA Guideline<br>EPA 540/09-01-123 | rat     | inhalation, 6 hrs, 14 wks    | 0, 500, 1500, 3000 ppm  | 10/sex (500 and 1500 ppm),<br>15/sex (3000 ppm) | No spontaneous mortality occurred during the study. Exposures to <i>n</i> -butyl acetate vapors resulted in acute, transient signs of reduced activity levels on a daily basis at 1500 and 3000 ppm, but no evidence of a cumulative effect on activity during the 14 week exposure. There was no evidence of neurotoxicity based on functional observational battery tests. The NOEL was 3000 ppm for this study.  | 61 FR 11414; 3/20/96, Docket#. 44622       |
| <i>n</i> -Butyl acetate | 123-86-4 | HESTOX<br>Inhalation Probe study                       | Non-TSCA Protocol/<br>Guideline         | rat     | inhalation, 6 hrs/day, 2 wks | 0, 750, 1500, 3000 ppm  | 15  | Exposure of groups of Five ad libitum-fed and 5 feed restricted males and 5 ad libitum-fed females to test substance produced concentration-related reductions in general activity levels during exposure, but no signs of toxicity after exposure. Animals appeared to acclimate to the 750 and 1500 ppm concentrations, but not to 3000 ppm. There were no apparent differences in the clinical conditions of ad libitum-fed and feed-restricted groups during or after exposure. The 3000 ppm feed-restricted group animals lost weight during the first week of the study, while animals in all other dose groups gained weight. The NOAEL was 750 ppm for this study.  | 61 FR13192; 3/26/96, Docket# OPPTS-44623   |

## Results of Testing

| Chemical Name | CAS No.  | Study Code/Type  | Protocol/Guideline                      | Species | Exposure                                      | Dose/Concentration     | No. per Group | Results   | Reference  |
|---------------|----------|--|---|---------|---|------------------------|---------------|---|--|
| Ethyl acetate | 141-78-6 | HENEUR<br>Functional Obser-<br>vational Battery, acute         | 1991 EPA Guideline<br>EPA 540/09-01-123 | rat     | inhalation, 6 hrs                             | 0, 600, 3000, 6000 ppm | 14/sex/dose   | No mortality was observed during the study. No overt clinical signs were noted during the exposure or observation period. Body weight loss was noted for both sexes in all dose groups on the day following exposure. Decreased absolute body weight was noted for both sexes from the 6000 ppm group following exposure. Body weight gains were observed for all exposure groups on subsequent days. Functional Observational Battery (FOB) findings were observed solely at the initial post-exposure measurement period in animals from the 3000 and 6000 ppm groups. FOB finding included drooping or closing eyelids, gait alterations, labored or audible breathing, decreased mean body temperature, hunched posture, decreased pupil size, piloerection, decreased mean forelimb grip strength, and sleeping during cageside observations. There were no gross lesions in any animal at necropsy. The NOEL for neurotoxicity was 600 ppm. | 60 FR 28409; 5/31/95,<br>Docket# OPPTS-<br>44617 |
| Ethyl acetate | 141-78-6 | HENEUR<br>Motor Activity, acute                                | 1991 EPA Guideline<br>EPA 540/09-01-123 | rat     | inhalation, 6 hrs                             | 0, 600, 3000, 6000 ppm | 14/sex/dose   | No mortality was observed during the study. No overt clinical signs were noted during the exposure or observation period. Body weight loss was noted for both sexes in all dose groups on the day following exposure. Decreased absolute body weight was noted for both sexes from the 6000 ppm group following exposure. Body weight gains were observed for all exposure groups on subsequent days. There were no gross lesions in any animal at necropsy. The NOEL for neurotoxicity was 600 ppm.  | 60 FR 28409; 5/31/95,<br>Docket# OPPTS-<br>44617 |
| Ethyl acetate | 141-78-6 | HENEUR<br>Functional Obser-<br>vational Battery,<br>subchronic | 1991 EPA Guideline<br>EPA 540/09-01-123 | rat     | inhalation, 6 hr/d, 5<br>d/wk for 99-100 days | 0, 350, 750, 1500 ppm  | Not reported  | Observations during exposure confirmed the presence of acute effects on nervous system function (diminished behavioral response to an alerting stimulus) at the 750 and 1500 ppm level. The FOB did not identify compound-related sensory or motor anomalies of toxicological relevance.  | 62 FR 42123; 8/5/97<br>Docket# OPPTS-<br>44642   |
| Ethyl acetate | 141-78-6 | HENEUR<br>Motor Activity,<br>subchronic                        | 1991 EPA Guideline<br>EPA 540/09-01-123 | rat     | inhalation, 6 hr/d, 5<br>d/wk for 99-100 days | 0, 350, 750, 1500 ppm  | Not reported  | Observations during exposure confirmed the presence of acute effects on nervous system function (diminished behavioral response to an alerting stimulus) at the 750 and 1500 ppm level. A statistically significant reduction in motor activity (23% reduction in total duration of movements) for 1500 ppm females during test week 13. Reduction in motor activity was judged to be a non-specific manifestation of systemic toxicity.  | 62 FR 42123; 8/5/97<br>Docket# OPPTS-<br>44642   |
| Ethyl acetate | 141-78-6 | HENEUR<br>Neuropathology,<br>subchronic                        | 1991 EPA Guideline<br>EPA 540/09-01-123 | rat     | inhalation, 6 hr/d, 5<br>d/wk for 99-100 days | 0, 350, 750, 1500 ppm  | Not reported  | Observations during exposure confirmed the presence of acute effects on nervous system function (diminished behavioral response to an alerting stimulus) at the 750 and 1500 ppm level. Neuropathological evaluation did not reveal any compound-related abnormalities. The LOEL for male rats was 350 ppm and NOEL was not demonstrated. The LOEL for female rats was 750 ppm and NOEL was 350 ppm.  | 62 FR 42123; 8/5/97<br>Docket# OPPTS-<br>44642   |

## Results of Testing

| Chemical Name    | CAS No.  | Study Code/Type  | Protocol/Guideline                      | Species | Exposure                                   | Dose/Concentration         | No. per Group                              | Results  | Reference  |
|------------------|----------|--|---|---------|--|----------------------------|--|--|--|
| Ethyl acetate    | 141-78-6 | HENEUR<br>Schedule Controlled<br>Operant Behavior              | 1991 EPA Guideline<br>EPA 540/09-01-123 | rat     | inhalation, 6 hr/d, 5<br>d/wk for 13 weeks | 0, 350, 750, 1500 ppm      | 10/males/group                             | There were no treatment-related effects on clinical observations or performance of operant task. The NOEL was determined to be 350 ppm, this value is associated with transient acute effects of exposure. Analysis of operant behavior did not reveal any cumulative or enduring effects on performance of complex behavioral task up to 1500 ppm.  | 62 FR 42123; 8/5/97<br>Docket# OPPTS-44642       |
| Isobutyl alcohol | 78-83-1  | HENEUR<br>Functional Obser-<br>vational Battery, acute         | 1991 EPA Guideline<br>EPA 540/09-01-123 | rat     | inhalation, 6 hrs                          | 0, 1500, 3000, 6000<br>ppm | 10/sex/dose                                | Isobutanol caused a rapidly reversible general depression of the central nervous system at concentration of 3000 and 6000 ppm during the exposure period. There were no treatment-related effects in rats at the 3000 ppm concentration following exposure. Minimal effects (hypoactivity) were seen in rats at 1500 ppm during, but not after exposure. No treatment-related findings were observed in any tissue or organ during gross necropsy. The LOEL was 1500 ppm.  | 59 FR 60985;<br>11/29/94, Docket#<br>OPPTS-44614 |
| Isobutyl alcohol | 78-83-1  | HENEUR<br>Motor Activity, acute                                | 1991 EPA Guideline<br>EPA 540/09-01-123 | rat     | inhalation, 6 hrs                          | 0, 1500, 3000, 6000<br>ppm | 10/sex/dose                                | Isobutanol caused a rapidly reversible general depression of the central nervous system at concentration of 3000 and 6000 ppm during the exposure period. The transient decrease in alertness in the female rats, transient decrease in motor activity in male and female rats, and transient, slight incoordinated gait observed in one male rat were considered residual anesthetic effects at 6000 ppm. The LOEL was 1500 ppm.  | 59 FR 60985;<br>11/29/94, Docket#<br>OPPTS-44614 |
| Isobutyl alcohol | 78-83-1  | HENEUR<br>Functional Obser-<br>vational Battery,<br>subchronic | 1991 EPA Guideline<br>EPA 540/09-01-123 | rat     | inhalation, 6 hr/d, 5<br>d/wk, 3 months    | 0, 250, 1000, 2500 ppm     | 15 (0, 2500<br>ppm); 10 (250,<br>1000 ppm) | There were no morphological or behavioral effects indicative of a persistent or progressive effect of isobutanol on the nervous system up to 2500 ppm. There were not treatment-related effects in the FOB during the study.   | 61 FR 17701; 4/22/96,<br>Docket# OPPTS-44624     |
| Isobutyl alcohol | 78-83-1  | HENEUR<br>Motor Activity,<br>subchronic                        | 1991 EPA Guideline<br>EPA 540/09-01-123 | rat     | inhalation, 6 hr/d, 5<br>d/wk, 3 months    | 0, 250, 1000, 2500 ppm     | 15 (0, 2500<br>ppm); 10 (250,<br>1000 ppm) | There were no morphological or behavioral effects indicative of a persistent or progressive effect of isobutanol on the nervous system up to 2500 ppm. There were not treatment-related effects on motor activity during the study.  | 61 FR 17701; 4/22/96,<br>Docket# OPPTS-44624     |
| Isobutyl alcohol | 78-83-1  | HENEUR<br>Neuropathology,<br>subchronic                        | 1991 EPA Guideline<br>EPA 540/09-01-123 | rat     | inhalation, 6 hr/d, 5<br>d/wk, 3 months    | 0, 250, 1000, 2500 ppm     | 20 (0, 2500<br>ppm); 10 (250,<br>1000 ppm) | There were no morphological or behavioral effects indicative of a persistent or progressive effect of isobutanol on the nervous system up to 2500 ppm. There were not treatment-related effects in neuropathology at the completion of this study. The only potential evidence of biologically significant subchronic toxicity in other organ systems was a slight increase in several hematological parameters in the 2500 female rats. A slight decrease in response to external stimuli was observed during exposure at all concentrations; this is thought to be a transient result of acute exposure to isobutanol. | 61 FR 17701; 4/22/96,<br>Docket# OPPTS-44624     |
| Isobutyl alcohol | 78-83-1  | HENEUR<br>Schedule Controlled<br>Operant Behavior              | 1991 EPA Guideline<br>EPA 540/09-01-123 | rat     | inhalation, 6 hr/d, 5<br>d/wk, 3 months    | 0, 250, 1000, 2500 ppm     | 10/sex/dose                                | Under the conditions of this study, there were no effects on performance under a 4 FR 20 - 2 FI 120 second schedule of food reinforcement after subchronic exposure to isobutanol at levels up to 2500 ppm.  | 61 FR 17701; 4/22/96,<br>Docket# OPPTS-44624     |



## Results of Testing

| Chemical Name          | CAS No.  | Study Code/Type  | Protocol/Guideline                   | Species                 | Exposure                            | Dose/Concentration                                   | No. per Group  | Results   | Reference                                  |
|------------------------|----------|--|--------------------------------------|-------------------------|-------------------------------------|--|----------------|---|--|
| Methyl isobutyl ketone | 108-10-1 | HENEUR<br>Schedule Controlled Operant Behavior           | 1991 EPA Guideline EPA 540/09-01-123 | rat                     | inhalation, 6 hr/day, 13 wks        | 0, 250, 750, 1500 ppm                                | 10/sex/dose    | Exposure to male rats to vapors of the test substance produced mild subchronic systemic effects and during exposure signs of reduced activity. However, this repeated exposure did not result in changes in Scheduled-Controlled Operant Behavior. The NOEL for subchronic neurotoxicity was 1500 ppm.  | 61 FR 42611; 8/16/96, Docket# OPPTS-44629  |
| Tetrahydrofuran        | 109-99-9 | HENEUR<br>Functional Observational Battery, acute        | 1991 EPA Guideline EPA 540/09-01-123 | rat                     | inhalation, 6 hrs                   | 0, 500, 2500, 5000 ppm                               | 12/sex/dose    | Transient sedation was the only effect seen at 2500 and 5000 ppm. The degree of sedation seen was concentration-dependent, and, following cessation of exposure, all test animals recovered. The NOEL was 500 ppm for this study.   | 61 FR 36378; 7/10/96, Docket# OPPTS-44628  |
| Tetrahydrofuran        | 109-99-9 | HENEUR<br>Motor Activity, acute                          | 1991 EPA Guideline EPA 540/09-01-123 | rat                     | inhalation, 6 hrs                   | 0, 500, 2500, 5000 ppm                               | 12/sex/dose    | Transient sedation was the only effect seen at 2500 and 5000 ppm. The degree of sedation seen was concentration-dependent, and, following cessation of exposure, all test animals recovered. The NOEL was 500 ppm for this study.   | 61 FR 36378; 7/10/96, Docket# OPPTS-44628  |
| Tetrahydrofuran        | 109-99-9 | HENEUR<br>Functional Observational Battery, subchronic   | 1991 EPA Guideline EPA 540/09-01-123 | rat                     | inhalation, 6 hr/d, 5 d/wk, 90 days | 0, 500, 1500, 3000 ppm                               | 18/sex/dose    | There were no biologically relevant, compound-related effects on FOB evaluation at any dose level. A diminished response to delivery of a punctate alerting stimulus at 1500 or 3000 ppm was transient and no clinical observations of comprised neurological function were detected when rats were immediately evaluated after removal from the exposure chambers. The NOEL was 500 ppm for both males and female rats based on clinical signs of sedation during exposure at 1500 and 3000 ppm. | 61 FR 67334; 12/20/96, Docket# OPPTS-44635 |
| Tetrahydrofuran        | 109-99-9 | HENEUR<br>Motor Activity, subchronic                     | 1991 EPA Guideline EPA 540/09-01-123 | rat                     | inhalation, 6 hr/d, 5 d/wk, 90 days | 0, 500, 1500, 3000 ppm                               | 18/sex/dose    | There were no biologically relevant, compound-related effects on motor activity evaluation at any dose level. The NOEL was 500 ppm for both males and female rats based on clinical signs of sedation during exposure at 1500 and 3000 ppm.   | 61 FR 67334; 12/20/96, Docket# OPPTS-44635 |
| Tetrahydrofuran        | 109-99-9 | HENEUR<br>Neuropathology, subchronic                     | 1991 EPA Guideline EPA 540/09-01-123 | rat                     | inhalation, 6 hr/d, 5 d/wk, 90 days | 0, 500, 1500, 3000 ppm                               | 18/sex/dose    | There were no biologically relevant, compound-related effects on morphological endpoints observed in the neuropathology evaluation. The NOEL was 500 ppm for both males and female rats based on clinical signs of sedation during exposure at 1500 and 3000 ppm.   | 61 FR 67334; 12/20/96, Docket# OPPTS-44635 |
| GMA                    | 106-91-2 | HEGTOXCHRM<br>Micronucleus Assay                         | 40 CFR 798.5395                      | mice                    | intraperitoneal injection           | 75, 150, 300 mg/kg                                   | 5/sex/dose     | GMA) was negative in the mouse micronucleus test  | 61 FR 3403; 1/31/96, Docket# OPPTS-44620   |
| GMA                    | 106-91-2 | HEGTOXMUTA<br>Gene mutations in Somatic cells in culture | 40 CFR 798.5300                      | Chinese hamsters, ovary | <i>in vitro</i>                     | 5 to 80 µg/mL (w/o S-9), 25 to 600 µg/mL (with S-9). | Not Applicable | GMA was negative in the CHO/HGPRT test in the absence of S-9 activation. However, it induced a weak positive response in the presence of S-9.   | 61 FR 3403; 1/31/96, Docket# OPPTS-44620   |

## Results of Testing

| Chemical Name | CAS No.     | Study Code/Type  | Protocol/Guideline   | Species                                      | Exposure                                   | Dose/Concentration  | No. per Group         | Results   | Reference  |
|---------------|-------------|--|--|--|--|---|-----------------------|---|--|
| GMA           | 106-91-2    | HENEUR<br>Neuropathology,<br>subchronic                        | 40 CFR 798.6400<br>(modified)                                  | rats   | inhalation, 6 hr/day. 5<br>d/wk, 13 weeks  | 0.5, 2, 15 ppm  | Not specified         | There were no treatment-related neurotoxic effects, including a comprehensive neuropathological examination, observed at any exposure level. Thus the NOEL was 15 ppm. At 4 weeks there was a low incidence of nasal discharge and enlarged nostrils at 2 and 15 ppm presumed to be related to nasal irritation.  | 61 FR 67334;<br>12/20/96, Docket#<br>OPPTS-44633 |
| GMA           | 106-91-2    | HENEUR<br>Motor activity,<br>subchronic                        | 40 CFR 798.6200<br>(modified)                                  | rats   | inhalation, 6 hr/day. 5<br>d/wk, 13 weeks  | 0.5, 2, 15 ppm  | Not specified         | There were no treatment-related neurotoxic effects, including motor activity, observed at any exposure level. Thus the NOEL was 15 ppm.   | 61 FR 67334;<br>12/20/96, Docket#<br>OPPTS-44633 |
| GMA           | 106-91-2    | HENEUR<br>Functional Obser-<br>vational Battery,<br>subchronic | 40 CFR 798.6050<br>(modified)                                  | rats   | inhalation, 6 hr/day. 5<br>d/wk, 13 weeks  | 0.5, 2, 15 ppm  | Not specified         | There were no treatment-related neurotoxic effects observed at any exposure level. Thus the NOEL was 15 ppm. In addition to the FOB evaluation, the post exposure neurotoxicity evaluation included evoked potential testing of the visual (FEP), auditory (ABR), and somatosensory system (SEP), and caudal nerves.  | 61 FR 67334;<br>12/20/96, Docket#<br>OPPTS-44633 |
| GMA           | 106-91-2    | HERTOXTERA<br>Developmental<br>toxicity                        | Non-TSCA<br>Protocol/Guideline<br>(see docket OPPTS<br>#42178) | New Zealand<br>White Rabbits<br>(time-mated) | inhalation, gestation<br>days 7 through 19 | 0.5, 2.0, 10.0 ppm  | 18 females            | There were no significant treatment-related effects on body weight, body weight gain, gross pathologic changes, or absolute or relative liver or kidney weights at any exposure level. Treatment-related degeneration of the nasal olfactory epithelium was present in the majority of rabbits from the 2 and 10 ppm groups. Erosions, ulcers of the olfactory and respiratory epithelium, and an increased incidence of subacute to chronic inflammation of the respiratory epithelium were noted in the 10 ppm group. The maternal NOEL for treatment-related histopathologic changes was 0.5 ppm. The NOEL for embryonal/fetal toxicity and teratogenicity was 10 ppm. | 61 FR 17700; 4/22/96,<br>Docket# OPPTS-<br>44624 |
| GMA           | 106-91-2    | HESTOX<br>Subchronic Toxicity                                  | Non-TSCA<br>Protocol/Guideline<br>(see docket OPPTS<br>#42178) | rats   | inhalation, 6 hr/day. 5<br>d/wk, 13 weeks  | 0.5, 2, 15 ppm  | 10/sex                | There were no treatment-related in-life observations noted during the 13-week exposure period. There were no significant treatment-related effects on body weight, urinalysis, clinical chemistry or hematology parameters, as well as gross pathological changes or organ weights at any exposure level. Histopathologically, slight hyperplasia of the respiratory epithelium of the nasal tissue was present in all rats at 15 ppm. There were no treatment-related effects at 0.5 or 2 ppm. Thus the NOEL was 2 ppm.  | 61 FR 5868811/18/96,<br>Docket# OPPTS-<br>44632  |
| AGE           | 120547-52-6 | HEGTOXCHRM<br>Micronucleus assay                               | 40 CFR 798.5295  | mice   | intraperitoneal<br>injection               | 1000, 2000, 4000 mg/kg<br>bw  | 5/sex                 | Slight reductions (up to 11%) in the ratio of polychromatic erythrocytes to total erythrocytes were observed. Results indicate that the test substance does not induce a significant increased in micronucleated polychromatic erythrocytes and was determined to be negative in the mouse micronucleus assay.  | 62 FR 39520; 7/23/97<br>Docket# OPPTS-<br>44641  |
| AGE           | 120547-52-6 | HEGTOXMUTA<br>Gene mutations in<br>somatic cells in culture    | 40 CFR 798.5300  | Chinese<br>hamster                           | in vitro                                   | 0.1 to 7.5 µg/ml without<br>activation and 0.5 to 50<br>µg/ml with activation | duplicate<br>cultures | AGE was tested both without and with exogenous metabolic activation in Chinese hamster ovary (CHO) cells at the HGPRT locus. AGE is not a gene mutagen in mammalian (CHO) cells in culture either without or with metabolic activation.   | 63 FR 25040; 5/6/98<br>Docket# OPPTS-<br>44648   |

## Results of Testing

| Chemical Name | CAS No.     | Study Code/Type  | Protocol/Guideline   | Species                           | Exposure                               | Dose/Concentration              | No. per Group               | Results   | Reference                                     |
|---------------|-------------|--|--|-----------------------------------|--|---------------------------------|-----------------------------|---|---|
| AGE           | 120547-52-6 | HEGTOXMUTA<br>Reverse Mutation<br>Assay                        | 40 CFR 798.5265  | <i>Salmonella<br/>typhimurium</i> | <i>in vitro</i>                        | 10-5000 ug/plate                | Not applicable              | The test material is a gene mutagen in prokaryotes in strain TA1535 with or without activation with a dose response. It was not mutagenic in other tested strains. [EPA]  | 63 FR 1464; 1/9/98<br>Docket# OPPTS-<br>44645 |
| AGE           | 120547-52-6 | HENEUR<br>Motor activity,<br>subchronic                        | 40 CFR 798.6200<br>(modified)                                  | F344 rat                          | dermal, 5 d/wk<br>13 weeks             | 1, 10, 100 mg/kg bw             | 12/sex                      | There was no evidence of treatment-related systemic toxicity and no effect on motor activity. The only treatment-related findings were skin irritation in mid- and high-dose rats. High-dose males had well-defined erythema, edema and scaling which severity decreased over the exposure period. Female in this group had less severe skin lesions. Mid-dose male and female rats had low incidence of very slight erythema and slight scaling. The NOEL for skin irritation was 1 mg/kg.   | 63 FR 1540; 3/31/98<br>Docket# OPPTS-         |
| AGE           | 120547-52-6 | HENEUR<br>Electrophysiology,<br>subchronic                     | Non-TSCA<br>Protocol/Guideline<br>(see docket OPPTS<br>#42185) | F344 rat                          | dermal, 5 d/wk<br>13 weeks             | 1, 10, 100 mg/kg bw             | 10/sex                      | There was a treatment-related change in flash-evoked potentials from the cerebellum (FEP-C) which showed dose-related and sex-related qualitative differences in waveforms. The early-latency components of the FEP-C were significantly smaller in mid- and high-dose male rats. The females had larger components than controls. Since the waveform changes might be due to the eye or optic nerve, the FEPs of the remaining male rats were examined at 5 weeks post-exposure. The dose-reponse pattern was still present and electroretinograms were collected from high-dose and control male rats; the high-dose rat ERGs were significantly smaller (38%) than controls. Histopathologic examination of retinas from high-dose male and female rats did not show any treatment-related pathologic alterations. The NOEL for this effect was 1 mg/kg. [EPA] | 63 FR 1540; 3/31/98<br>Docket# OPPTS-         |
| AGE           | 120547-52-6 | HENEUR<br>Neuropathology,<br>subchronic                        | 40 CFR 798.6400<br>(modified)                                  | F344 rat                          | dermal, 5 d/wk<br>13 weeks             | 1, 10, 100 mg/kg bw             | 5/sex                       | There were no treatment-related gross or histopathologic lesions in the central or peripheral nervous system. [EPA]   | 63 FR 1540; 3/31/98<br>Docket# OPPTS-         |
| AGE           | 120547-52-6 | HENEUR<br>Functional Obser-<br>vational Battery,<br>subchronic | 40 CFR 798.6050<br>(modified)                                  | F344 rat                          | dermal, 5 d/wk<br>13 weeks             | 1, 10, 100 mg/kg bw             | 12/sex                      | There were no treatment-related neurotoxic effects observed at any dose level. There were no significant differences among groups in grip strength, landing foot splay or rectal temperature. [EPA]   | 63 FR 1540; 3/31/98<br>Docket# OPPTS-         |
| AGE           | 120547-52-6 | HERTOXTERA<br>Developmental<br>Toxicity screen                 | Non-TSCA<br>Protocol/Guideline<br>(see docket OPPTS<br>#42185) | Sprague-dawley<br>rat             | dermal, 6 hr/d,<br>gestation days 6-15 | 1, 10, 50, 100, 200<br>mg/kg bw | 8 females/group<br>pregnant | Dermal irritation at the application site was noted in rats from the three highest doses. The severity and time of onset were dose-related. No maternal or developmental toxicity was apparent at any dose level and the NOEL for these effects was at least 200 mg/kg. The NOEL for maternal dermal irritation was 10 mg/kg. [EPA]   | 63 FR 1464; 1/9/98<br>Docket# OPPTS-<br>44645 |

## Results of Testing

| Chemical Name | CAS No.     | Study Code/Type  | Protocol/Guideline   | Species        | Exposure                                    | Dose/Concentration                                 | No. per Group  | Results   | Reference  |
|---------------|-------------|--|--|----------------|---|--|----------------|---|--|
| AGE           | 120547-52-6 | HESTOX<br>Subchronic Toxicity<br>with testicular<br>assessment | Non-TSCA<br>Protocol/Guideline<br>(see docket OPPTS<br>#42185) | F344 rat       | dermal, 90-day<br>6hr/d, 5d/wk, 13<br>weeks | 1, 10, 100 mg/kg bw                                | 10/sex/dose    | There was no evidence of systemic toxicity. Detailed examination of both testes and spermatogenic cycle staging did not reveal testicular toxicity. The application site from the high dose rats showed dermal irritation, scaling and fissuring. Histologic examinations of the skin showed hyperkeratosis, epidermal hyperplasia, and a mild subacute to chronic inflammatory response. The rats from the 10 mg/kg group had slight scaling at the application site during the final week of the study, but no histopathologic changes. The NOEL for dermal irritation was 1 mg/kg. [EPA]   | 63 FR 1464; 1/9/98<br>Docket# OPPTS-<br>44645    |
| DGEBPA        | 1675-54-3   | EFTSPT<br>Glove permeability<br>test                           | ASTM F 739-91  | Not applicable | 8 hr  | neat DGEBPA and 3<br>mixtures containing<br>DGEBPA | Not applicable | Of the chemically protective gloves tested for permeation resistance to DGEBPA, Safety 4 4H EVAL laminated glove and North B-174 butyl rubber gloves would offer the most protection since they prevented permeation during the 8-hr period with all 4 test substances. The remaining gloves (Edmont 8-352 neoprene, Pioneer AF-18 nitrile, and Edmont 4-412 PVC) showed no breakthrough with DGEBPA resin while exhibiting mean breakthrough times with the 3 mixtures ranging from 9 to 50 min. Following breakthrough, the Edmont 4-412 showed degradation with all 3 mixtures as evidenced by liquid penetration after 30-126 min of contact. Edmont 8-352 showed liquid penetration after 360 minutes of contact with DGEBPA/ alkyl C <sub>12</sub> -C <sub>14</sub> glycidyl ether mixture. | received 7/31/95                                 |
| DGEBPA        | 1675-54-3   | HECTOXCARC<br>2-year Bioassay                                  | 40 CFR 798.3320<br>(modified)                                  | rat            | dermal                                      |  |                |   | due 12/98  |
| DGEBPA        | 1675-54-3   | HENEUR<br>Functional Obser-<br>vational Battery,<br>subchronic | 40 CFR 798.6050<br>(modified)                                  | rat            | dermal, 13 wks                              | 10, 100, 1000 mg/kg                                | 12/sex         | The only effect clearly related to treatment was a decrease in body weight at 1000 mg/kg in both sexes. The NOEL for dermal exposure to DGEBPA was 100 mg/kg for both male and female rats.   | 61 FR 36378; 7/10/96,<br>Docket# OPPTS-<br>44628 |
| DGEBPA        | 1675-54-3   | HENEUR<br>Neuropathology,<br>subchronic                        | 40 CFR 798.6400<br>(modified)                                  |                | dermal, 13 wks                              | 10, 100, 1000 mg/kg                                | 12/sex         | The only effect clearly related to treatment was a decrease in body weight at 1000 mg/kg in both sexes. The NOEL for dermal exposure to DGEBPA was 100 mg/kg for both male and female rats.   | 61 FR 36378; 7/10/96,<br>Docket# OPPTS-<br>44628 |
| DGEBPA        | 1675-54-3   | HENEUR<br>Motor activity,<br>subchronic                        | 40 CFR 798.6200<br>(modified)                                  |                | dermal, 13 wks                              | 10, 100, 1000 mg/kg                                | 12/sex         | The only effect clearly related to treatment was a decrease in body weight at 1000 mg/kg in for both sexes. The NOEL for dermal exposure to DGEBPA was 100 mg/kg for both male and female rats.   | 61 FR 36378; 7/10/96,<br>Docket# OPPTS-<br>44628 |
| DGEBPA        | 1675-54-3   | HERTOXTERE<br>Reproductive Toxicity                            | 40 CFR 798.4700<br>(modified)                                  | rat            | gavage, 14 wks (P1),<br>12 wks (P2)         | 50, 540, 750 mg/kg                                 | 30/sex         | Administration of DGEBPA to adult rats resulted in a decrease in body weight in the 540 (males) and 750 mg/kg (males and females) dose groups in both generations. Secondary changes in absolute and/or relative and liver and kidney weights were also observed in these dose groups. There were no treatment-related histologic changes noted nor effects on reproductive performance in any dose group. The NOEL for adult males was 50 mg/kg and 540 mg/kg for adult females. The NOEL for reproductive effects was 750 mg/kg for this study.   | 61 FR 25224; 5/20/96,<br>Docket# OPPTS-<br>44626 |

## Results of Testing

| Chemical Name                     | CAS No.   | Study Code/Type                          | Protocol/Guideline            | Species  | Exposure  | Dose/Concentration  | No. per Group  | Results  | Reference  |
|-----------------------------------|-----------|--|-------------------------------|--|---|---|--|--|--|
| DGEBPA                            | 1675-54-3 | HESTOX<br>Subchronic Toxicity            | 40 CFR 798.2250<br>(modified) | rat  | dermal, 13 wks  | 10, 100, 1000 mg/kg   | 10/sex, 10<br>female (satellite<br>group at 1000<br>mg/kg) | DGEBPA applied to the skin of rats five time per week for approximately 13 weeks caused no apparent systemic toxicity with the exception of decreased body weight and body weight gain in males and females at 1000 mg/kg. Food consumption was also slightly lower. Increased serum cholesterol values were noted in mid- and high dose 1 rats, but were considered of questionable toxicological significance since no correlated histopathological changes were observed. Female rats in the high-dose satellite group dosed 3 times per week showed no signs of systemic toxicity. Epidermal hyperplasia with chronic inflammation, characterized as chronic dermatitis, was observed histopathologically at all dose levels for male rats and in female rats at 100 and 1000 mg/kg dose levels and the high-dose satellite group. | 61 FR 36378; 7/10/96,<br>Docket# OPPTS-<br>44628 |
| DGEBPA                            | 1675-54-3 | HESTOX<br>Subchronic Toxicity            | 40 CFR 798.2250<br>(modified) | B6C3F1 mice  | dermal, 13 wks  | 1, 10, 100 mg/kg  | 10   | DGEBPA applied to the skin of male mice 3 times per week for 13 weeks caused no apparent systemic toxicity. Mild to moderate chronic active dermatitis with a weak dose-response was observed at dosages up to 100 mg/kg. Spongiosis and epidermal micro abscess formation indicated that the maximum-tolerated dose was met in mice administered 100 mg/kg DGEBPA.  | 61 FR 25224; 5/20/96,<br>Docket# OPPTS-<br>44626 |
| Octamethylcyclo-<br>tetrasiloxane | 556-67-2  | EEATOX<br>Acute fish toxicity            | 40 CFR 797.1400<br>(modified) | rainbow trout  | flow-through, 14 days   | 2.9, 4.4, 6.9, 12, 22<br>µg/L (mean measured)                 | Not specified  | Exposure under near-saturated conditions (20 to 30 µ/L = soluble limit) identified a 14-day LC <sub>50</sub> of 10.0 (8.5-13) µg/L.  | 55 FR 3482; 2/01/90<br>Fiche# OTS0525576         |
| Octamethylcyclo-<br>tetrasiloxane | 556-67-2  | EEATOX<br>Mysid shrimp acute<br>toxicity | 40 CFR 797.1930               | <i>Mysidopsis<br/>bahia</i> (mysid<br>shrimp)                | flow-through, 96 hrs  | 1.6, 2.2, 3.7, 9.1 µg/L<br>(mean measured)                    | Not specified  | Tests at the limit of solubility did not lead to mortality.  | 55 FR 3482; 6/05/90<br>Fiche# OTS0525578         |
| Octamethylcyclo-<br>tetrasiloxane | 556-67-2  | EEATOX<br>Daphnid acute toxicity         | 40 CFR 797.1300               | <i>Daphnia<br/>magna</i><br>(waterflea)                      | flow-through, 48 hrs  | 1.7, 2.9, 3.7, 7.8, 15<br>µg/L (mean measured)                | Not specified  | At the limit of solubility, no lethal or sublethal effects were noted. A NOEC of 15 µg/L was identified.   | 55 FR 22947; 6/05/90<br>Fiche# OTS0525579        |
| Octamethylcyclo-<br>tetrasiloxane | 556-67-2  | EEATOX<br>Algae acute toxicity           | 40 CFR 797.1050<br>(modified) | <i>Selenastrum<br/>capricornutum</i><br>(freshwater<br>alga) | 96 hrs  | 22 µg/L   | Not applicable   | The mean cell density in cultures exposed to a saturated test solution for 96-hours was 82% of the mean cell density in control cultures.  | Study due 5/05/90<br>Fiche#<br>OTS0525579        |
| Octamethylcyclo-<br>tetrasiloxane | 556-67-2  | EEATOX<br>Acute fish toxicity            | 40 CFR 797.1400<br>(modified) | sheepshead<br>minnow   | flow-through, 14 days   | 1.3, 1.6, 2.3, 4.2, 6.3<br>µg/L (mean measured)               | Not specified  | The 14-day LC <sub>50</sub> was >6.3 µg/L, the limit of water solubility.  | 55 FR 22947; 6/05/90<br>Fiche# OTS0525578        |
| Octamethylcyclo-<br>tetrasiloxane | 556-67-2  | EEATOX<br>Algae acute toxicity           | 40 CFR 797.1050<br>(modified) | <i>Selenastrum<br/>capricornutum</i><br>(green alga)         | Culture medium under<br>constant illumination,<br>96 hrs                | Saturated solution,<br>measured initially at 22<br>to 23 µg/L | Not applicable   | The mean cell density in exposed cultures was significantly reduced to 82% that of the controls. Cell densities increased over time in all replicates.   | 55 FR 22947; 6/05/90<br>Fiche# OTS0525579        |
| Octamethylcyclo-<br>tetrasiloxane | 556-67-2  | EEBIOC<br>Fish bioconcentration          | 40 CFR 797.1520               | fathead minnow   | closed system, 6 days,<br>followed by depura-<br>tion period of 14 days | 0.50 µg/L (nominal)   | Not specified  | Mean measured daily BCF was 3,800 (± 840)X. A steady-state BCR was not attained during the study. The half-life of C-14 residues could not be calculated; at 14 days, an average of 61% of accumulated C-14 residues remained in the tissues.  | 56 FR 40614; 8/15/91<br>Fiche# OTS0525577        |

## Results of Testing

| Chemical Name                | CAS No.  | Study Code/Type                                 | Protocol/Guideline                                    | Species                                    | Exposure  | Dose/Concentration   | No. per Group                         | Results  | Reference                                  |
|------------------------------|----------|---|---|--|---|--|---------------------------------------|--|--|
| Octamethylcyclotetrasiloxane | 556-67-2 | EECLIF<br>Fish early life stage                 | 40 CFR 797.1600                                       | <i>Oncorhynchus mykiss</i> (rainbow trout) | 93 days (60 days post-hatch)  | 0.25, 0.53, 1.1, 1.9, 4.4 µg/L (mean)  | 56/group, except for 4.4 µg/L with 62 | Rainbow trout survival at the completion of the hatching period (day 33) in all concentrations ranged from 79 to 85% and was statistically comparable to the survival of the control organisms (80%). Larval survival among all concentrations ranged from 90-100%. There were no significant difference between the treatment levels and the control. The mean total length and wet weight of larvae ranged from 53 to 54 mm and from 1.5 to 1.6 g. The no observed effect concentration was determined to be 4.4 µg/L. | 56 FR 5688; 1/12/91<br>Fiche# OTS0531503   |
| Octamethylcyclotetrasiloxane | 556-67-2 | EECTOX<br>Chronic aquatic invertebrate toxicity | 40 CFR 797.1330                                       | <i>Daphnia magna</i> (waterflea)           | flow-through, 21 days   | 1.7, 1.8, 4.2, 7.9, 15, 23 µg/L (mean measured)                                    | Not specified                         | No effects were noted on survival at any concentration tested. EC <sub>50</sub> (immobilization) was >15 µg/L and the LOEC was 15 µg/L. No effects were noted at 7.9 µg/L. The MATC was determined to be ≥ 7.9 and ≤ 15 µg/L. The saturation level in test water was 26 µg/L.  | 55 FR 22947; 6/05/90<br>Fiche# OTS0525579  |
| Octamethylcyclotetrasiloxane | 556-67-2 | EECTOX<br>Chironomid sediment toxicity          | 40 CFR 795.4050 (modified)                            | <i>Chironomus tentans</i> (midge)          | flow-through in high organic carbon sediment, 14 days                 | 8.0, 24, 80, 240, 800 mg/kg (nominal); 2.6, 7.4, 19, 54, 170 mg/kg (mean measured) | Not specified                         | Lowest observed effect concentration (LOEC) was 170 mg/kg mean measured; no observed effect concentration (NOEC) was 54 mg/kg. The Maximum Acceptable Toxicant Concentration (MATC) was >54 mg/kg and <170 mg/kg (geometric mean MATC = 96 mg/kg).   | 56 FR 20224; 5/02/91<br>Fiche# OTS0531486  |
| Octamethylcyclotetrasiloxane | 556-67-2 | EFBDEG<br>Microcosm biodegradation              | 40 CFR 796.3401(modified)                             | pond sediment and water                    | aerobic, 56 days  | 30 µg/L (nominal)  | Not applicable                        | At the solubility limit, OMCTS did not appear to be susceptible to biodegradation under test conditions.   | Fiche# OTS0531504                          |
| Octamethylcyclotetrasiloxane | 556-67-2 | EFPCHEWSOL<br>Water solubility                  | 40 CFR 796.1860                                       | Not applicable                             | seawater at 25 °C, water generator column                             | Not specified  | Not applicable                        | Solubility = 33 ± 3.6 µg/L   | 54 FR 51322; 12/14/89<br>Fiche# OTS0525575 |
| Octamethylcyclotetrasiloxane | 556-67-2 | EFPCHEWSOL<br>Water solubility                  | 40 CFR 796.1860                                       | Not applicable                             | freshwater (ASTM Type II), water generator column                     | Not specified  | Not applicable                        | Solubility = 74 ± 9.4 µg/L   | 54 FR 51322; 12/14/89<br>Fiche# OTS0525575 |
| Octamethylcyclotetrasiloxane | 556-67-2 | EFTSPTVOLZ<br>Volatilization from water         | 40 CFR 796.2770 (modified)                            | Not applicable                             | Measurements taken at six stirrer speeds ranging from 200 to 400 rpm. | 45 µg/L  | Not applicable                        | The measured ratio of the volatilization rate (k <sub>v</sub> ) to the oxygen reation rate (k <sub>o</sub> ) was 0.57 ± 0.17. This value is similar to that of other familiar, widely-used solvents such as benzene, chloroform, and trichloroethylene and suggests that OMCTS will have a similar aquatic half-life to these solvents   | Fiche# OTS0525564                          |
| Tetrabromobisphenol A        | 79-94-7  | EEATOX<br>Algae acute toxicity                  | Non-TSCA Protocol/Guideline (see docket #OPTS-42083A) | <i>Chlorella sp.</i> (green alga)          | 6 algal growth media; 96 hrs  | 1.5 mg/L (estimated saturation concentration)                                      | Not applicable                        | The test material did not inhibit growth by as much as 50% in any growth medium.   | 53 FR 49227; 12/6/88<br>Fiche# OTS0525468  |
| Tetrabromobisphenol A        | 79-94-7  | EEATOX<br>Acute fish toxicity                   | 40 CFR 797.1400 (modified)                            | fathead minnow                             | flow-through; 144 hrs   | 0.19, 0.26, 0.32, 0.45, 0.63 mg/L  | 20 (10/replicate)                     | Total mortality was observed at the high dose level. The 96-hour LC <sub>50</sub> value was 0.54 mg/L, and the 144-hour LC <sub>50</sub> was 0.49 mg/L. No effects were observed at 0.26 mg/L.   | 53 FR 49227; 12/6/88<br>Fiche# OTS0525512  |

## Results of Testing

| Chemical Name          | CAS No. | Study Code/Type                               | Protocol/Guideline  | Species  | Exposure   | Dose/Concentration                                   | No. per Group              | Results  | Reference   |
|------------------------|---------|---|---|--|--|--|----------------------------|--|---|
| Tetrabromo-bisphenol A | 79-94-7 | EEATOX<br>Chironomid sediment toxicity        | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42083A) | <i>Chironomus tentans</i> (midge)              | flow-through in 3 sediment types (high, medium, and low organic carbon); 14 days         | 0, 13, 25, 50, 100, 200 (nominal)                    | 50 (25/replicate)          | Survival in all treated sediments ranged from 44 to 96% after 14 days of exposure. No effects were noted on growth (wet weight). The highest no-effect levels for high, medium, and low organic carbon sediments were, 0.046, 0.045, and 0.039 mg/L, respectively.   | 54 FR 38436; 9/18/89<br>Fiche# OTS0525519                     |
| Tetrabromo-bisphenol A | 79-94-7 | EEATOX<br>Acute oyster toxicity               | 40 CFR 797.1800   | <i>Crassostrea virginica</i> (eastern oysters) | flow-through; 96 hrs   | 0, 75, 100, 160, 260, 310 µg/L                       | 40 (20/replicate)          | The 96-hour EC <sub>50</sub> based on decreased shell growth (and 95% confidence limits) were 98 (20-210) µg/L. The no effect concentration was <18 µg/L.  | 54 FR 28837; 7/10/89<br>Fiche# OTS0525515                     |
| Tetrabromo-bisphenol A | 79-94-7 | EEBIOC<br>Mollusk bioconcentration            | 40 CFR 797.1830   | <i>Crassostrea virginica</i> (eastern oysters) | flow-through; 20 day   | 1.0 µg/L (nominal)                                   | 60                         | The concentration of <sup>14</sup> C-residues reached steady state by day 5. The bioconcentration factor was 720X. Half-life of <sup>14</sup> C-residues occurred between days 3 and 5 of depuration.  | 54 FR 28837; 7/10/89<br>Fiche# OTS0525518                     |
| Tetrabromo-bisphenol A | 79-94-7 | EEBIOC<br>Fish Bioconcentration study         | 40 CFR 797.1520   | fathead minnow                                 | flow-through; 24 days  | 0, 5.0 µg/L  | 91/group                   | Steady state was reached on day 4 of exposure. The mean steady-state tissue concentration was 5800 µg/kg, which established a BCF of 1200X. Half-life of the <sup>14</sup> C-residues occurred during the first 24 hours of depuration.  | 54 FR 14861; 4/13/89<br>Fiche# OTS0525518                     |
| Tetrabromo-bisphenol A | 79-94-7 | EECLIF<br>Fish early life stage study         | 40 CFR 797.1600 (modified)                                  | fathead minnow                                 | flow-through; 35 days  | 0.024, 0.040, 0.084, 0.16, 0.31 mg/L (mean measured) | 120 embryos (60/replicate) | Based on significant adverse effects (p≤0.05) on embryo survival and larval survival, the MATC was >0.16 and <0.31 mg/L.   | 54 FR 38436; 9/18/89<br>Fiche# OTS0525518<br>Doc.# 40-8998118 |
| Tetrabromo-bisphenol A | 79-94-7 | EECTOX<br>Chronic invertebrate toxicity       | 40 CFR 797.1330   | <i>Daphnia magna</i>                           | flow-through; 21 days  | 0.056, 0.10, 0.19, 0.30, 0.98 mg/L                   | 40 (20/replicate)          | Reproduction was the most sensitive indicator of toxicity. No effects were noted at ≤0.30 mg/L. The maximum acceptable toxicant concentration (MATC) was >0.30 mg/L and <0.98 mg/L.  | 54 FR 38436; 9/18/89<br>Fiche# OTS0525517                     |
| Tetrabromo-bisphenol A | 79-94-7 | EFBDEG<br>Microcosm biodegradation (Eco Core) | Non-TSCA<br>Protocol/Guideline<br>(see docket #OPTS-42083A) | Not applicable                                 | aerobic sediment/ water microbial test system (natural core chambers), 56 days           | 10, 100, 1000 µg/L                                   | Not applicable             | Biodegradation occurred in all tested concentrations as determined by HPLC with radiometric detection. Half-lives ranged between 48 and 84 days with a correlation between half-life and TBBPA concentration and microbial population. Less than 8% of applied radioactivity was recovered as CO <sub>2</sub> . Filtered water contained less than 5% of applied radioactivity. At test termination, 44.7%, 64.2% and 60.8% at 10, 100 and 1000 µg/L treatment levels, respectively. | 54 FR 38436; 9/18/89,<br>Docket# OPPTS-44537                  |
| Tetrabromo-bisphenol A | 79-94-7 | EFBDEG<br>Biodegradation study                | 40 CFR 796.3400   | Not applicable                                 | aerobic soil (sandy loam, clay loam, silty loam); 64 days in biometer flasks at 21.5 °C. | 0.5 mg/100 µL  | Not applicable             | The amounts of parent compound remaining in the soil after 64 days for sandy, clay, and silty loam were 74.3 to 81.9%, 41.1 to 43.2%, and 35.9, to 40.1%, respectively. For all soil types, 6.0% or less of the applied radioactivity was recovered in the CO <sub>2</sub> traps, suggesting only partial biodegradation (products were not identified in report).   | 54 FR 8816; 3/2/89<br>Fiche# OTS0525513                       |

## Results of Testing

| Chemical Name              | CAS No.  | Study Code/Type                           | Protocol/Guideline  | Species        | Exposure  | Dose/Concentration  | No. per Group  | Results  | Reference                               |
|----------------------------|----------|---|---|----------------|---|---|----------------|--|---|
| Tetrabromo-bisphenol A     | 79-94-7  | EFBDEG<br>Biodegradation study            | 40 CFR 796.3400   | Not applicable | anaerobic soil (sandy loam, clay loam, silty loam); 64 days | 0.5 mg/100 µL   | Not applicable | The amounts of parent compound remaining in the soil after 64 days for sandy loam, clay loam, and silty loam were 43.7 to 57.0%, 89.5 to 90.6%, and 53.4 to 65.0%, respectively, as determined by TLC analysis. For all soil types, 0.5% or less of the applied radioactivity was recovered in the CO <sub>2</sub> traps, indicating an incomplete conversion to CO <sub>2</sub> and/or other volatile products. Based on the results obtained, TBBPA is susceptible to biodegradation in soils under aerobic conditions under the conditions and procedures employed in the study.  | 54 FR 8816; 3/2/89<br>Fiche# OTS0525513 |
| Ethyl tertiary butyl ether | 637-92-3 | HEADME<br>Pharmacokinetics                | Non-TSCA Protocol/<br>Guideline (see docket# OPTS-42099A) | rats           | inhalation; single 6 hr, nose only                          | 500, 750, 1000, 1750, 2500, 5000 ppm  | 3/sex/dose     | The majority of absorbed <sup>14</sup> C was eliminated by 48 hours after exposure. The total amount of <sup>14</sup> C eliminated was proportional to the exposure concentration. At all exposure concentrations, 96-98% of the total amount excreted was eliminated in the urine or exhaled as volatile organics. The balance of the radioactivity was found in the feces and exhaled CO <sub>2</sub> . However, as exposure concentrations increased from 500 to 1750 ppm, the biological processes for the elimination and absorption of inhaled ethyl tertiary butyl ether became saturated.                          | Fiche# OTS0557695                       |
| Ethyl tertiary butyl ether | 637-92-3 | HEADME<br>Pharmacokinetics                | Non-TSCA Protocol/<br>Guideline (see docket# OPTS-42099A) | mice           | inhalation; single 6 hr, nose only                          | 500, 750, 1000, 1750, 2500, 5000 ppm  | 3/sex/dose     | The majority of absorbed <sup>14</sup> C was eliminated by 48 hours after exposure. The total amount of <sup>14</sup> C eliminated was proportional to the exposure concentration up to 2500 ppm. At all exposure concentrations, 83-93% of the total amount excreted was eliminated in the urine or exhaled as volatile organics. The balance of the radioactivity was found in the feces and exhaled CO <sub>2</sub> . However, as exposure concentrations increased from 500 to 1750 ppm and above, the biological processes for the elimination and absorption of inhaled ethyl tertiary butyl ether became saturated. | Fiche# OTS0557696                       |
| Ethyl tertiary butyl ether | 637-92-3 | HEGTOXCHRM<br>Bone marrow micronucleus    | Non-TSCA Protocol/<br>Guideline (see docket# OPTS-42099A) | mice           | inhalation; 6 hr/d; 5 days                                  | 0, 400, 2000, 5000 ppm  | 5/sex/group    | The test substance did not produce significant, exposure-related increases in the frequency of micronucleated PCE in mice assessed 24 hours after termination of the final exposure. Therefore, the test substance was not considered to be an inducer of micronuclei under the conditions the test..  | Fiche# OTS0557636                       |
| Ethyl tertiary butyl ether | 637-92-3 | HEGTOXMUTA<br>Chromosome aberration assay | Non-TSCA Protocol/<br>Guideline (see docket# OPTS-42099A) | hamsters       | <i>in vitro</i>   | 0.10, 0.30, 1.0, 3.0 and 5.0 mg/ml both in the absence and presence of metabolic activation.  | Not applicable | Treatment of cultured CHO cells with the test substance did not result in statistically significant or concentration-related increases in the frequencies of chromosome aberrations either in the presence or in the absence of a rat liver S9 metabolic activation system. Therefore, the test substance was not considered to be clastogenic under the test conditions.  | Fiche# OTS0557635                       |
| Ethyl tertiary butyl ether | 637-92-3 | HEGTOXMUTA<br>Forward mutation assay      | Non-TSCA Protocol/<br>Guideline (see docket# OPTS-42099A) | hamsters       | <i>in vitro</i>   | 0.10, 0.30, 1.0, 3.0 and 5.0 mg/ml, both in the absence and presence of metabolic activation. | Not applicable | No statistically significant or concentration-related increases in mutation frequencies were observed at any of the concentrations tested, either in the absence or in the presence of S9 activation. Therefore, the test substance was not considered to be mutagenic to cultured CHO cells under the test conditions.  | Fiche# OTS0557634                       |



## Results of Testing

| Chemical Name | CAS No. | Study Code/Type                            | Protocol/Guideline  | Species                          | Exposure  | Dose/Concentration  | No. per Group  | Results  | Reference  |
|---------------|---------|--|---|----------------------------------|---|---------------------|----------------|--|--|
| Nitrobenzene  | 98-95-3 | HECTOXCARC<br>Carcinogenicity              | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>47004) | F344 rats                        | inhalation, 6 hr/day, 5<br>d/wk for 107 weeks                 | 0, 1, 5, 25 ppm     | Not reported   | The test substance was determined to be carcinogenic. In male rats, the incidence of hepatocellular adenoma, hepatocellular adenoma or carcinoma, and renal tubular adenoma were increased. In addition, male rats had a marginally increased incidence of thyroid follicular neoplasia (adenoma or adenocarcinoma). In females, the incidence of endometrial stromal polyp was increased. Exposure was also associated with increased incidence of nasal mucosa, blood, liver and testis effects. Other toxic effects noted included methemoglobinemia and hepatic effects. | Docket# OPPTS-<br>47044, Chemical<br>Industry Institute of<br>Toxicology (CIIT)  |
| Nitrobenzene  | 98-95-3 | HECTOXCARC<br>Carcinogenicity              | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>47004) | CD rats (male)                   | inhalation, 6 hr/day, 5<br>d/wk for 107 weeks                 | 0, 1, 5, 25 ppm     | Not reported   | The test substance was determined to be carcinogenic. In male rats, the incidence of hepatocellular adenoma and hepatocellular adenoma or carcinoma were increased. Exposure was also associated with increased incidence of nasal mucosa, blood, liver and testis effects. Other toxic effects included methemoglobinemia, hepatic effects, and testicular atrophy.   | Docket# OPPTS-<br>47044, CIIT  |
| Nitrobenzene  | 98-95-3 | HECTOXCARC<br>Carcinogenicity              | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>47004) | B6C3F <sub>1</sub> mice          | inhalation, 6 hr/day, 5<br>d/wk for 107 weeks                 | 0, 5, 25, 50 ppm    | Not reported   | The test substance was determined to be carcinogenic. In male mice, the incidence of alveolar/bronchiolar adenoma, alveolar/bronchiolar carcinoma, and thyroid adenoma were increased. In female mice, the incidence of mammary gland adenocarcinoma was increased and a marginally increased incidence of hepatocellular adenoma. Exposure was also associated with increased incidence of nasal mucosa, blood, liver and testis effects. Other toxic effects included methemoglobinemia, hepatic effects, and testicular atrophy.  | Docket# OPPTS-<br>47044, CIIT  |
| Nitrobenzene  | 98-95-3 | HEGTOXCHRM<br>Chromosomal<br>aberration    | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>47004) | chinese hamster<br>(ovary cells) | <i>in vitro</i> , with and<br>without metabolic<br>activation | ≤1600 µg/ml in DMSO | Not applicable | Test results were negative, with and without S9 metabolic activation.  | National Toxicology<br>Program (NTP)<br>unpublished results  |
| Nitrobenzene  | 98-95-3 | HEGTOXDNAF<br>Sister chromatid<br>exchange | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>47004) | chinese hamster<br>(ovary cells) | <i>in vitro</i> , with and<br>without metabolic<br>activation | ≤1600 µg/ml in DMSO | Not applicable | Test results were negative, with and without S9 metabolic activation.  | NTP unpublished<br>results.  |
| Nitrobenzene  | 98-95-3 | HEGTOXMUTA<br>Mutagenicity                 | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>47004) | <i>Salmonella</i>                | <i>in vitro</i> , with and<br>without metabolic<br>activation | up to 1000 µg/plate | Not reported   | Test results indicate nitrobenzene is not a gene mutagen in the <i>Salmonella</i> /Ames test both with and without metabolic activation in strains TA98, TA100, TA1535, TA1537.  | Haworth, S, T Lawlor,<br>K Mortelmans, W<br>Speck and E Zeiger.<br>1983. Environmental<br>Mutagenesis 5(Suppl.<br>1):23-142. |

## Results of Testing

| Chemical Name | CAS No. | Study Code/Type                    | Protocol/Guideline  | Species                      | Exposure  | Dose/Concentration | No. per Group | Results  | Reference   |
|---------------|---------|------------------------------------|---|------------------------------|---|--------------------|---------------|--|---|
| Nitrobenzene  | 98-95-3 | HERTOXTERA<br>Teratogenicity study | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>47004) | rats                         | inhalation, 6 hr/d, 5<br>d/wk for 10 weeks,<br>treatment continued<br>with 6 hr/d, 7 days/wk<br>for 2-wk mating<br>period, a 19-day<br>gestation period<br>(females only), and<br>17-day postpartum<br>period (dams only) | 0, 1, 10, 40 ppm   | 30/sex/group  | Treatment with the test substance compromised the reproduction of rats at 40 ppm, due to toxic effects in the testes of males. The NOEL was established at 10 ppm regarding reproduction and fertility in rats.  | Fiche# OTS0510653,<br>The Nitrobenzene<br>Association Project<br>Report 47-524  |
| Nitrobenzene  | 98-95-3 | HERTOXTERA<br>Teratogenicity study | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>47004) | rats                         | inhalation, gestation<br>days 6-15  | 0, 1, 10, 40 ppm   | Not reported  | There was no maternal, embryo or fetotoxicity at 1 ppm, and no embryo or fetotoxicity (including teratogenicity) at 10 and 40 ppm, although these concentrations produced some maternal toxicity.  | Fiche# OTS0510652,<br>The Nitrobenzene<br>Association Project<br>Report 47-522  |
| Nitrobenzene  | 98-95-3 | HERTOXTERA<br>Teratogenicity study | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>47004) | rabbits                      | inhalation, 6 hr/d on<br>gestation days 7-19  | 10, 40, 100 ppm    | 22/group      | At 10 ppm, the test substance produced no maternal toxicity, embryotoxicity or teratogenicity. At 40 ppm, the test substance produced some maternal toxicity (increased methemoglobin levels and increased liver weights); however, no embryotoxicity or teratogenicity was indicated. At 100 ppm, the test substance produced maternal toxicity (increased methemoglobin levels and liver weights) and some embryotoxicity (increased resorption data); however, no teratogenicity was indicated. | Fiche# OTS0510651,<br>The Nitrobenzene<br>Association Project<br>Report 83-2725 |
| Nitrobenzene  | 98-95-3 | HESTOX<br>Subchronic toxicity      | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>47004) | CD (Sprague-<br>Dawley) rats | inhalation, 6 hr/day, 5<br>d/wk for 90 days   | 0, 5, 16, 50 ppm   | Not reported  | There was no effect on body weight gain or mortality. Mean serum methemoglobin concentrations were significantly elevated in 16 and 50 ppm male rats and 50 ppm female rats. The liver was affected (centrilobular hepatocyte hypertrophy) in rats. The testicles had bilateral degeneration of seminiferous epithelium and a reduction or absence of sperm in the epididymis.   | Docket# OPPTS-<br>47044, CIIT   |
| Nitrobenzene  | 98-95-3 | HESTOX<br>Subchronic toxicity      | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>47004) | F-344 rats                   | inhalation, 6 hr/day, 5<br>d/wk for 90 days   | 0, 5, 16, 50 ppm   | Not reported  | There was no effect on body weight gain or mortality. Mean serum methemoglobin concentrations were significantly elevated in 5, 16, and 50 ppm male rats and 16 and 50 ppm female rats. The liver was affected (centrilobular necrosis and disorganization of hepatic cord) at 50 ppm. The testicles had bilateral degeneration of seminiferous epithelium and a reduction or absence of sperm in the epididymis.  | Docket# OPPTS-<br>47044, CIIT   |
| Nitrobenzene  | 98-95-3 | HESTOX<br>Subchronic toxicity      | Non-TSCA Protocol/<br>Guideline (see<br>docket# OPTS-<br>47004) | B6C3F <sub>1</sub> mice      | inhalation, 6 hr/day, 5<br>d/wk for 90 days   | 0, 5, 16, 50 ppm   | Not reported  | There was no effect on body weight gain or mortality. Mean serum methemoglobin concentrations were significantly elevated in 50 ppm rats. Cellular vacuolization of the zona reticularis of the adrenal was found in females at 5 ppm, and increased in severity with dose. Male mice has increased severity of liver lesions (centrilobular hepatocyte hyperplasia).  | Docket# OPPTS-<br>47044, CIIT   |